- on, not the type of studies the EPA should shun.
- 2 These are the studies that will guarantee that
- 3 communities don't suffer from the devastating
- 4 impacts of dirty water and polluted air. Studies
- 5 like these establish the original limits for lead,
- 6 and this research continues to essential today.
- 7 This proposed rule may seem abstract, but
- 8 it is anything but that. And it is extremely
- 9 significant. It will have far-reaching -- far-
- 10 reaching impacts on the ability of EPA to protect
- 11 all of us and our families. And it could affect
- our most important environmental safeguards. It
- is extremely personal, for my mom, for my family,
- 14 and for me.
- I am here today to ask you to withdraw
- 16 this proposed rule and recommit to EPA's mission
- of protecting human health and the environment.
- 18 Thank you for the opportunity to speak today.
- MS. Hall: Thank you. Would Speaker
- Number 22, Ms. Nsedu Obot Witherspoon, and Speaker
- Number 23, Joanne Zurcher, please come up to the
- speaker's table. And Speaker Number 24, Michelle

- 1 Endo and Speaker Number 25, Jenny Xie, I think,
- please take a seat at the on-deck chairs.
- 3 [Substitution of panel members.]
- 4 MR. ROBBINS: Good morning. I'm Chris
- 5 Robbins. I'm the Acting Deputy Assistant
- 6 Administrative for Management in the Office of
- 7 Research and Development.
- 8 MS. ORME-ZAVALETA: Good morning.
- 9 MR. ROBBINS: Thank you.
- MS. DOA: Good morning. My name is Maria
- 11 Doa , I am in the Office of Research and
- 12 Development.
- MS. WITHERSPOON: Good morning. I'm
- 14 Nsedu Obot Witherspoon. I'm the Executive
- 15 Director for the Children's Environmental Health
- 16 Network. My name is spelled N-S-E-D-U O, B as in
- 17 boy, O-T W-I-T-H-E-R-S-P-O-O-N.
- For over 26 years, the Children's
- 19 Environmental Health Network, also known as CEHN,
- 20 has been a national voice committed to protecting
- 21 all children from the harmful effects of
- 22 environmental hazards, and to promoting a

- 1 healthier environment.
- 2 CEHN educates decision makers and
- 3 advocates for evidence-based child protective
- 4 policies. We also ensure that those who care for
- 5 children, personally or professionally, have the
- 6 information they need to take the steps to reduce
- 7 children's exposures to harmful toxicants.
- As the Executive Director, and on behalf
- 9 of CEHN, I appreciate the opportunity to provide
- 10 these comments on the EPA proposed rule,
- "Strengthening Transparency in Regulatory
- 12 Science."
- 13 CEHN is strongly opposed to the rule and
- is concerned that it will adversely affect EPA's
- ability to use the best available science in
- 16 decision-making, and negatively influence existing
- 17 and future protections for children's health, such
- 18 as clean air, clean water, and the prevention of
- 19 toxic exposures.
- The exposed rule sets transparency
- 21 standards that are too rigid and impossible to
- meet. It requires that all data used in

- 1 rulemaking be publicly made available, and allows
- 2 EPA to exclude data that relies on confidential
- 3 patient information. Critical studies which have
- 4 led to significant advancements in protective
- 5 policies, for example from the NIEHS, EPA's
- 6 Children's Environmental Health, and Disease
- 7 Prevention Research Centers may very well be
- 8 excluded.
- The scientific research that EPA uses
- 10 already undergoes a long-established transparent
- 11 review process, and makes available the scientific
- 12 studies it relies on to inform policy. Sometimes
- 13 studies contain private medical data that legally
- 14 can't and should not be made public. In those
- 15 cases, independent review bodies have also
- 16 examined the studies and weighed in on the
- 17 research. No legitimate reason exists to exclude
- 18 those studies and their critical important
- 19 findings.
- 20 Health based research involves people and
- often the collection of private information.
- 22 There are no systems in place to protect this

- 1 information. The federal government must continue
- 2 to protect private information about patients, and
- 3 not allow this information to be made public.
- 4 Otherwise, patients will not participate in these
- 5 important studies.
- 6 Further, redacting personal information
- 7 actually sounds easy, however, it is cumbersome
- 8 and quite costly. EPA will not likely have the
- 9 resources to redact personal information resulting
- in exclusion of critical studies.
- 11 The proposed rule would restrict EPA's
- 12 ability to set regulations informed by
- 13 confidential data that cannot be replicated. This
- is of serious concern because for many older,
- 15 long-standing landmark studies, the original data
- 16 sets were either not maintained, or stored in out
- of date formats. These could be eliminated under
- 18 this proposed rule.
- The proposed rule could block the use of
- 20 studies on the harmful impacts of toxic exposures
- 21 and pollution. Studies which were instrumental in
- 22 the Clean Air Act, the Safe Drinking Water Act,

- 1 and the -- excuse me, Food Quality Protection Act,
- 2 among many others. We do request that you
- 3 withdraw this proposal, "Strengthening
- 4 Transparency and Regulatory Science." If the
- 5 proposed rule is implemented, an inevitable
- 6 consequence is that children that could have been
- 7 protected from chemical exposures will lose those
- 8 opportunities.
- 9 Irreversible damage to children in their
- 10 growth and development, loss of intelligence,
- 11 behavior modifications, and overall life
- 12 achievement is the future ahead, and I would hope,
- not the legacy that this EPA would like to
- 14 preserve. Thank you very much.
- MR. ROBBINS: Thank you.
- MS. ZURCHER: My name is Joanne Zurcher,
- 17 J-O-A-N-N-E Z-U-R-C-H-E-R, and I'm representing
- 18 the National Environmental Health Association.
- 19 Good morning. Thank you for the
- 20 opportunity to speak to you on behalf of the
- 21 environmental health professionals from across the
- 22 country who've vigorously opposed the Censoring

- 1 science rule.
- My name is Joanne Zurcher, and I am the
- 3 Director of Government Affairs for the National
- 4 Environmental Health Association, NEHA.
- 5 Environment health is profoundly local.
- 6 Simply put, it's the cleanliness of the water from
- 7 the kitchen faucets. It's the safety of the food
- 8 we feed our families, our friends, and ourselves.
- 9 It's the air the children breath during the 1,600
- 10 hours they spend inside their schools. It's the
- 11 cleanliness of our community beaches that our
- 12 families are spending the summer enjoying.
- When things go well, environmental health
- is not on the front page of the New York Times,
- 15 because environmental health professionals keep us
- 16 safe every single day.
- NEHA has over 7,000 members. Our members
- anticipate, recognize, evaluate, and control
- 19 hazards that are likely to cause harm, serious
- 20 illness, or even death to American families.
- 21 Examples include lead, radon, legionella viruses,
- 22 harmful algae blooms, PFOA, PFOS, Zika viruses,

- 1 and many other natural and man-made risks. Our
- 2 members possess strong science and math
- 3 backgrounds. They must take over 30 units of
- 4 undergraduate math and science just to sit for our
- 5 exam. They have the unique ability to work with
- 6 clinical and nonclinical professionals. They know
- 7 and work with the regulated community. They are
- 8 credentialed members of the profession, and the
- 9 NEHA credential is considered the gold standard.
- 10 EPA science is the foundation for
- informed decision-making for our members. Our
- 12 members turn to the EPA for best practices. Our
- 13 members rely on EPA research to promote their
- 14 community's health.
- Our communities see EPA as the shelter of
- 16 scientific certainty in an era of uncertainty.
- 17 Our members rely on EPA expertise, whether it's
- 18 continuing -- excuse me, containing mercury spills
- in their homes, setting standards to keep toxic
- 20 chemicals out of drinking water, or cleaning up
- 21 super fund sites, just to name a few of the few
- 22 activities we do together. EA professionals work

- 1 closely with the EPA every step of the way.
- The EPA has administered successfully,
- 3 the Clean Water Act, and the Clean Air Act, and
- 4 these acts should be expanded based on scientific
- 5 research. The EPA should not be working to
- 6 undermine scientific research. Instead, this EPA
- 7 should be working to provide running water to the
- 8 630,000 American families who do not have running
- 9 water in their homes.
- Let's be clear, this proposed rule
- undermines the EPA's mission to protect human
- 12 health. Now is not the time to compromise health
- of our nation by casting a shadow of uncertainty
- on the integrity of the EPA -- of EPA's research.
- EPA research is globally recognized as
- 16 the foundation for informed decision-making that
- 17 affects every person the plant. NEHA and it's
- 18 7,000 members are in every community and territory
- in the nation. Every EH professional relies on
- 20 EPA research to ensure constituents meet human --
- 21 meet their human potential.
- The current research system works, which

- 1 at once protects the identity of every research
- participant, while promoting the health of every
- 3 American. Health research sometimes includes
- 4 sensitive data from patients, such as medical
- 5 history and geographic location, which must be
- 6 continued to be private and protected. Crucial
- 7 volunteers will cease to come forward for
- 8 scientific research if their medical history and
- 9 geographic information will be made public, thus
- 10 putting critical scientific research at risk.
- 11 Please do not destroy a national gem, our EPA
- research, because you, your family, and your
- 13 community deserve no less than a fully functional
- 14 research system that protects and identifies
- 15 research subjects while promoting the health of
- 16 the nation.
- NEHA and the environmental health
- 18 professionals from across the United States
- 19 vigorously oppose the censoring scientific rule.
- 20 Thank you for this opportunity to be heard on this
- important topic, and please remember, do no harm.
- MR. ROBBINS: Thank you.

- MS. HALL: Would Speaker Number 24,
- 2 Michelle Endo, and speaker Number 25, Jenny Xie,
- 3 come up to the speaker's table. And Speaker
- 4 Number 26, Ann Mesnikoff, and Speaker Number 27,
- 5 Roy Gamse, please take a seat at the speaker's --
- 6 well, at the on-deck chairs.
- 7 Speakers are reminded to speak into the
- 8 mic and state your organization.
- 9 MS. ENDO: My name is Michelle Endo, E-N-
- 10 D-O, and I'm speaking in a personal capacity, but
- 11 I'm an intern at the Environmental Defense Fund.
- So my name is Michelle Endo, and I'm a
- 13 second-year student at Georgetown Law. I'm also a
- 14 legal intern at the Environmental Defense Fund
- 15 here in Washington, D.C. I'm here today to offer
- 16 comments on my own behalf and to present my grave
- 17 concerns with EPA's proposed rule, "Strengthening
- 18 Transparency in Regulatory Science."
- 19 I'm a fourth generation Southern
- 20 Californian who lived the first 18 years of my
- 21 life in Northern Los Angeles County. And while
- 22 I'm proud to be from the Golden State, it also

- 1 means that I grew up breathing some of the worst
- 2 air pollution in the nation. Despite tremendous
- 3 improvement, 70 percent of Californians live in an
- 4 area with unhealthy air. As a result, I also grew
- 5 to be familiar with the dangers of air pollution
- 6 and the importance of health-protective
- 7 regulation.
- 8 My family lives in a town that, like much
- 9 of LA County, is in the United States 98th
- 10 percentile for tropospheric ozone, according to
- 11 EPA's own Environment Justice Screen.
- 12 Tropospheric ozone, commonly referred to
- as smog, is the visible layer of air pollution
- 14 that gives LA sunsets their famous striped hues.
- 15 Several studies have consistently reported there
- is a significant association between ozone
- 17 pollution and premature death. According to the
- 18 American Lung Association, long-term exposure to
- ozone pollution is also linked to developmental
- 20 harm, reproductive harm, cardiovascular harm, and
- increased susceptibility to infections.
- While I never had a snow day before

- 1 moving to D.C., like most SoCal kids, I'm very
- 2 familiar with bad air days. Instead of playing
- 3 outside and building snowmen, children in Southern
- 4 California lose all outdoor playtime on bad air
- 5 days in order to avoid the harmful effects of
- 6 smog. Coughing, impaired athletic performance,
- 7 eye irritation, chest pain, nausea, headaches, and
- 8 respiratory congestion.
- 9 Smoggy days can also worse asthma, heart
- 10 disease, bronchitis, and emphysema.
- My sister and I enjoyed the early years
- of childhood with fewer complications relative to
- my neighbor peers. But before even starting high
- 14 school we both had missed days of school for nose
- 15 bleeds that were likely triggered by the
- irritating smog that settled in the valley, and
- 17 because ozone forms by the interaction of sunlight
- 18 with hydrocarbons and nitrogen oxides emitted from
- 19 cars and trucks, bad air days tended to worse each
- 20 year, our Southern California summers, broke
- 21 standard heat records of years before.
- Shortly after my sister joined the high

- 1 school soccer team, my family started to notice
- 2 that her once limitless stamina on the field was
- wearing down. One particularly hot and hazy day,
- 4 she had no choice but to walk off the field in the
- 5 middle of the match. Clutching her chest, she
- 6 struggled to breath. We later learned that she
- 7 had developed asthma from LA's unhealthful smog,
- 8 like many of our friends and family in the area.
- 9 It was experiences like this that
- motivated my decision to study environmental
- 11 policy in college, and that continued to drive my
- 12 legal career. Having witnessed first-hand the way
- in which the geography of where one lives, plays,
- 14 learns, works, and grows determines one's health
- outcomes, I could not have chosen another path in
- 16 good conscience.
- When I first chose this path, over eight
- 18 years ago, my hope was to strengthen the laws and
- 19 regulations that did not go far enough to protect
- 20 my family and our environment.
- Under the Clean Air Act, EPA was required
- to establish and regularly update federal

- 1 standards for hazardous air pollutants, including
- 2 asthma-causing particulate matter and ozone.
- 3 These standards and the National Ambient Air
- 4 Quality Standards or NAAQS, form the backbone of
- 5 our nation's air quality protections. Although
- 6 the NAAQS did not prevent my sister's asthma, they
- 7 have and continue to bring about substantial
- 8 improvement in our nation's air quality since
- 9 their first formulation.
- The EPA's proposed rule would have
- 11 excluded peer review studies that form the
- 12 scientific basis of NAAQS. For example, peer
- 13 reviewed studies would be excluded because the
- underlying data and models cannot be disclosed,
- 15 even in partial form. In fact, the standards
- would not have been issued had the proposed rule
- 17 been in place when they were first enacted in the
- 18 1970s, because EPA would have tossed out the
- 19 underlying studies, tying its hands from taking
- 20 action in imminent public health concerns.
- Without a doubt, many more Southern
- 22 Californians would have had their lives altered,

- 1 or even cut short by dangerous levels of air
- 2 pollution.
- If adopted, the proposed rule would
- 4 deprive EPA policy makers from real world evidence
- 5 and studies that are vital to the EPA's review of
- 6 the NAAQS into the future. Further, the proposal
- 7 directly contravenes the comprehensive federal and
- 8 state regulatory program congress envisioned when
- 9 drafting the Clean Air Act of 1970. It reduces
- 10 our public health legislation to mere
- 11 declarations, as EPA would severely delayed if not
- rendered entirely unable to establish future
- 13 standards using the best available science.
- Generations before me, through
- 15 legislation like the Clean Air Act, recognize that
- 16 public health and environmental pollution required
- 17 strong federal leadership and expert agencies like
- 18 EPA. Departing from the Agency's practice of
- 19 scientific review for over the last 40 years,
- 20 practices aligned with national and
- intergovernmental bodies, like the Royal Society
- of Medicine, and the World Health Organization,

- 1 jeopardizes EPA's ability to utilize its expertise
- with high cost to people's health.
- It is therefore troubling that the Agency
- 4 has proposed to take this action under the guise
- 5 of scientific integrity without consulting its own
- 6 panel of scientific experts, the Science Advisory
- 7 Board, and against the advice of leading
- 8 scientific journals and organizations. It is even
- 9 more troubling when considering the Agency's
- 10 recent practices toward the public and the press,
- 11 which have been far from transparent.
- To me, it is clear the proposal's
- 13 purported goal of transparency is a pretext for
- the Agency's attempt to shirk its statutory
- 15 command. For the health of my sister, my friends,
- 16 and all Americans, I urge EPA to abandon this
- 17 proposed rule. Thank you.
- MR. ROBBINS: Thank you.
- MS. XIE: Good morning. My name is Jenny
- 20 Xie, J-E-N-N-Y, last name X-I-E, and I'm a policy
- intern at the Environment Defense Fund, but I'm
- 22 here today speaking from a personal capacity to

- 1 express my personal opposition to EPA's proposed
- z rule, "Strengthening Transparency in Regulatory
- 3 Science."
- 4 Many of the activities that I am involved
- 5 in on campus involve holding the university
- 6 accountable for its environmental goals that it
- 7 has set. I'm currently a student at Cornell
- 8 University, studying English and Environmental
- 9 Sustainability Sciences.
- In fact, one of the main initiatives that
- 11 I am involved in calls for the University to
- 12 disclose as a financial investments and fossil
- 13 fuels in order to increase transparency, have
- 14 accountability, and maintain integrity as it works
- 15 towards its carbon neutrality. It is therefore
- incredibly disheartening to hear that this EPA
- 17 administration is championing a proposed rule that
- 18 claims to be for increased transparency, when in
- 19 fact the purpose and the fact of the proposed
- 20 would be to bar EPA from considering rigorous
- 21 public health science and reduce the transparency
- of EPA's scientific analysis.

- The proposed rule would require the EPA
- base some of its most important regulatory
- decisions only upon does response studies where
- 4 the underlying data can be disclosed. The reality
- 5 is that key scientific studies backing our
- 6 nation's critical clean air safeguards which
- 7 protect our health and environment are based on
- 8 confidential patient data that in many cases
- 9 cannot be disclosed in any form.
- These rigorous peer-reviewed state of the
- 11 art studies could be improperly discarded should
- 12 this rule be finalized. As many scientists have
- noted, this would undermine and not promote the
- 14 use of sound science in EPA decisions. Just
- 15 because the data underlying a study isn't
- 16 published does not mean that the study cannot be
- 17 verified using other means.
- For example, the American Cancer
- 19 Society's Cancer Prevention Study II, tracked air
- 20 pollution, exposure, and personal medical
- 21 histories of nearly 670,000 people for more than
- two decades to understand the exact risk of air

- 1 pollution on death.
- The study was based on private patient
- 3 information that cannot be publicly disclosed, and
- 4 yet the study has been subject to reanalysis and
- 5 its conclusions have been upheld. And allowed
- 6 under the scientific journal does response, the
- 7 authors listed 16 key studies alone which
- 8 supported the original conclusion of the Cancer
- 9 Prevention Study 2.
- Even more concerning is the fact that the
- 11 proposed rule provides the administrator with
- 12 broad discretion to make exception to the policy
- on a case-by-case basis. Former Administrator
- 14 Pruitt may be out of office now, but Acting
- 15 Administrator Wheeler's record as a fossil fuel
- 16 lobbyist for corporations like Murray Energy
- 17 leaves me and others incredibly skeptical that
- 18 this rule would be applied fairly with no concrete
- 19 criteria guiding decision to grant an exception.
- This part of the proposal raises a
- 21 serious risk that this or future administrations
- 22 could selectively waive the policy to build a

- 1 distorted scientific record that is designed to
- 2 reach a desired result. In fact, just a few weeks
- 3 ago I was in Pennsylvania where I'm from, talking
- 4 to an Uber driver. He's a father with a daughter
- 5 who has asthma, and we talked about the EPA. He
- 6 had worked in public service before and expressed
- 7 to me how frustrated he was with the current
- 8 administration, with the EPA, and how it seemed
- 9 that despite the endless promises the
- 10 administration has made to protect its citizens
- and better our lives, many of those promises were
- not being fulfilled.
- I can't help but think how disappointed
- 14 he would be if he knew that the EPA has proposed a
- 15 rule which will make it more difficult for EPA to
- use the best science to protect the health of him
- 17 and his family. Citizens are watching and aware,
- 18 from parents, to scientists, to students like me
- 19 who advocate for good policy on their own college
- 20 campuses.
- The EPA hastily shuttled this rule past
- even the OMB, but it must pause to hear the

- 1 concerns of the public. EPA's proposal will lead
- 2 to censored science, not transparent science.
- 3 Thank you for the opportunity to testify on the
- 4 proposed rule today.
- MR. ROBBINS: Thank you.
- 6 MS. HALL: Would Speaker Number 26, Ann
- 7 Mesnikoff, and Speaker Number 27, Roy Gamse, come
- 8 up to the speaker's table. And Speaker Number 28,
- 9 Jennifer Sabb (sic), and Speaker Number 29, Paul
- 10 Miller, please take your seat at the on-deck
- 11 chairs.
- MS. MESNIKOFF: Hi. I'm Ann Mesnikoff.
- 13 It's M-E-S-N-I-K-O-F-F, and A-N-N, no E.
- Good morning. I'm Ann Mesnikoff. I'm
- 15 the Federal Legislative Director for the
- 16 Environmental Law and Policy Center.
- 17 ELPC works throughout the Great Lakes and
- 18 the Midwest, protecting public health and special
- 19 places under the belief that environmental
- 20 protection and economic development can be
- 21 achieved together.
- ELPC appreciates the opportunity to

- 1 testify in opposition to EPA's proposal to censor,
- 2 or otherwise constrain the science it will
- 3 consider in issuing essential standards that are
- 4 meant to protect public health and our
- 5 environment. The Midwest and the Great Lakes
- 6 region, with its industrial and agricultural
- 7 heritage is impacted by environmental and public
- 8 health challenges to air, land, and water, and we
- 9 depend upon EPA to effectively implement
- 10 environmental laws to protect the public and our
- 11 environment.
- There is no basis in existing bedrock
- 13 environmental laws that authorizes EPA to limit
- 14 science considered in rulemaking processes. EPA
- 15 cites several key laws in its justification for
- 16 this proposal. Nowhere in the cited statutes is
- 17 there a basis for demanding access to raw data,
- nor does this relate sensibly to any definition of
- 19 best available science. Rather, this undermines
- 20 the use of best available science called for in
- 21 environmental statutes, including the Clean Air
- 22 Act.

- 1 Further, there is no basis for
- politically appointed administrators to choose
- 3 which science will be considered, and which may
- 4 not be. EPA should continue to apply the rigorous
- 5 standards the Agency has used for decades, and
- 6 that stakeholders engage in the process that is
- 7 full and open with regards to science.
- 8 EPA's Science Advisory Board voted to
- 9 review this action during its June 1st meeting.
- 10 This proposal has also prompted, as we've heard
- 11 today, vehement reaction from the scientific
- 12 community. EPA's proposal is not about
- 13 transparency. It is about undermining public
- 14 health. The negative effects of this proposed
- 15 rule on EPA's programs could be far reaching
- 16 across the Midwest. Midwesterners are exposed to
- unhealthy levels of air pollutants, including
- 18 particulates, ozone, and toxic emissions from our
- 19 industries and agricultural operations.
- 20 Achieving and maintaining health air to
- 21 breath remains a challenge. EPA just finalized
- not attainment designations for Midwest's biggest

- 1 cities. There are millions of people -- where
- 2 millions of people live, work, and play.
- 3 Foundational studies about the impact of air
- 4 pollution to public health are essential. These
- 5 studies have been reviewed numerous times. Yet,
- 6 under EPA's proposal, they would be ruled out of
- 7 bounds, compromising the Agency's ability to truly
- 8 assess the impacts of air pollution and to set
- 9 standards are a level that will protect public
- 10 health as the Clean Air Act requires.
- 11 Weaker standards will mean dirtier air in
- our communities. The elimination of these studies
- 13 would also skew the evaluation of cost and
- 14 benefits, leading to less protective rules that
- will not be based on a true accounting of the
- 16 public health costs of pollution. We're also
- 17 concerned about how EPA's proposal to censor
- 18 science will impact a range of other significant
- 19 concerns across the Midwest and Great Lakes, from
- 20 using the best available science and its review of
- 21 toxic -- the toxic insecticide, chlorpyriphos, the
- 22 impacts of growing problems of harmful algael

- 1 blooms in Lake Erie and other places across the
- 2 Great Lakes on public health, and in setting
- 3 standards for lead in water, soil, and in homes.
- 4 EPA has shown time and again that
- 5 achieving cleaner air, and water, and a healthier
- 6 environment go hand-in-hand with economic growth.
- 7 Our children's health across the Midwest depends
- 8 on EPA continuing to do its job and not let
- 9 industry-driven agenda undermine its essential
- 10 role. We respectfully ask EPA to withdraw this
- 11 proposal. We will be submitting more detailed
- 12 comments to the record. Thank you.
- MR. ROBBINS: Thank you.
- MR. GAMSE: I am Roy Gam -- I am Roy
- 15 Gamse, G-A-M-S-E, no S on the end. Formerly EPA
- 16 Deputy Assistant Administrator. Reading the
- 17 comments of John Bachmann of the Environmental
- 18 Protection Network. He served EPA for 33 years,
- 19 was Associate Director of Science Policy and New
- 20 Programs for the Office of Air Quality Planning
- 21 and Standards.
- John's comments. "I appreciate the

- 1 opportunity to provide the comments on the
- proposed rulemaking on strengthening transparency
- 3 on behalf of EPN. EPN will submit the detailed
- 4 written comments on the proposal later."
- 5 "This proposal would not strengthen
- 6 transparency of regulations. Instead, it would
- 7 preclude the assessment and use of best scientific
- 8 information available as required by all major
- 9 statutes administered by EPA. The process by
- which it was developed, the misuse of references
- 11 that ultimately do not support its arguments and
- 12 the lack of specifics, what EPA actually intends
- to do are an embarrassment to the agency."
- "The new acting administration should
- 15 withdraw it from consideration as soon as
- 16 possible. EPA's proposal is a solution in search
- of a problem. A proposal asserts it's dealing
- 18 with a replication crisis, but does not cite a
- 19 single instance where a study used by EPA for any
- 20 type of major rule was shown to be flawed due to a
- 21 lack of access to the underlying data. In fact,
- 22 EPA and the industry funded an independent

- 1 reanalysis of the two air pollution studies that
- were criticized for not releasing confidential
- 3 health information, and both were successfully
- 4 reproduced with the results published in 2000.
- 5 Moreover, their key findings have been replicated
- 6 dozens of times since then by other investigators
- 7 using different health and air quality data."
- 8 "The proposal to exclude important peer
- 9 reviewed studies is wholly inconsistent with
- 10 scientific practice and EPA's past use of science
- and regulatory decisions, where studies with novel
- results appear, EPA's assessments have noted
- 13 limitations and some cases supported reanalysis."
- "EPA's science policy related assessments
- are, themselves, peer-reviewed by the SAB or CASAC
- 16 to further ensure study evaluations consider all
- of the relevant scientific literature."
- "As noted by the SAB workgroup, the EPA's
- 19 proposal downplays valid concerns about the risks
- 20 of providing access to the confidential
- information of subjects in epidemiology studies.
- 22 The SAB group noted some of the largest most

- 1 useful health effects data sets cannot be made
- 2 fully public because certain personal information
- of age, sex, health, and location could be used to
- 4 identify participants, or because of agreements
- 5 made with study participants in advance."
- "EPA failed to mention various ways to
- 7 assess the validity of fire epidemiology studies
- 8 without access to data, nor that the rule may
- 9 preclude continued use of studies published many
- 10 years ago."
- "The proposal includes a provision for
- 12 the administrator to waive this requirement. No
- 13 clear decision criteria provided to allow EPA
- 14 scientists and stakeholders to understand when and
- 15 how the waivers would be granted. It appears that
- 16 requirement could be applied in an arbitrary and
- 17 capricious manner that does not reflect sound
- 18 science judgment. Critical decisions like these
- must be made on the basis of science, not
- 20 politics. Otherwise, highly relevant studies for
- which data can't be publicly shared, even if
- 22 published in the best peer reviewed journals and

- 1 replicated may be judged to be inherently
- untrustworthy."
- "The rushed, mostly secret process EPA
- 4 followed in developing the proposal displays a
- 5 complete disinterest in transparency, much less in
- 6 science. In developing this proposal EPA
- 7 leadership did not provide a role for zone career
- 8 science experts in crafting the proposal, never
- 9 included the rule on its regulatory agenda, did
- not notify of consult with the SAB, much less
- 11 request the review as required by law. Did not
- 12 solicit the advice of the NAS on provisions that
- would change does response models used in risk
- 14 assessment from those previously recommended by
- NAS, did not ask for review to solicit the views
- of other federal agencies that conduct research or
- use health effect science in developing
- 18 regulations. Finally, the Agency originally only
- 19 allowed a 30-day comment period on this remarkable
- unvetted departure from the past practice."
- "In suggesting potential cost of the rule
- would be minimal, EPA ignored the cost to

- 1 researchers who would have to pay to set up and
- 2 maintain data sharing for their previously
- 3 published studies to be considered, to EPA for
- 4 conducting the multiple reanalysis required in
- 5 Section 30.6 of the rule, and to public health for
- 6 the disbenefits of undermining existing
- 7 regulations. Having done no assessment, EPA has
- 8 no basis for its claim that the benefits of the
- 9 rule exceed its cost. Scientists and scientific
- 10 publications that EPA cites as evidence for
- 11 support for this rule have rejected the proposal's
- 12 preemption of existing studies based on
- availability of raw data. Professor John
- 14 Ioannidis reacted strongly to the proposal in an
- 15 editorial noting that, quote, 'If the proposed
- 16 rule is approved, science will be practically
- 17 eliminated from all decision-making processes.
- 18 Regulation would then depend uniquely on opinion
- 19 and whim.' End quote."
- "Editors of four major scientific
- 21 journals whose policies EPA cited as support
- jointly stated, quote, 'It does not strengthen

- 1 policies based on scientific evidence to limit the
- 2 scientific evidence that can inform them.
- 3 Excluding relevant studies simply because they
- 4 don't meet rigid transparency standards will
- 5 adversely affect decision-making processes.'"
- 6 "Finally, EPA should immediately withdraw
- 7 this flawed proposal from consideration, given the
- 8 fatal flaw of establishing unnecessary regulation
- 9 for science assessment that would elevate
- 10 transparency over any other criterion. We're
- unable to offer any suggests for improving it."
- MR. ROBBINS: Thank you.
- MS. HALL: Would Speaker Number 28,
- 14 Jennifer Sabb (sic), and Speaker Number 29, Paul
- 15 Miller, come up to the speaker's table. And
- 16 Speaker Number 30, Matthew McKinzie and Speaker
- 17 Number 31, Anne Mellinger-Bird (sic), take a seat
- 18 at the on-deck chairs.
- 19 Please remember to speak into the mic and
- 20 state your organization.
- MS. SASS: Hello. My name is Jennifer
- 22 Sass, S-A-S-S. I'm with NRDC, the Natural

- 1 Resources Defense Council.
- 2 And I'm here to talk about the concern
- 3 that scientists and environment health and medical
- 4 professionals have with this rule. In one of his
- 5 last acts of aggression against the public before
- 6 resigning, the corrupt and disgraced EPA
- 7 Administrator Scott Pruitt, proposed the rule to
- 8 restrict the scientific studies that EPA could
- 9 rely on to set safety standards for toxic
- 10 chemicals.
- 11 Ironically, the rule is called science
- 12 transparency when in truth public health will be
- 13 seriously harmed. That's why over 40 doctors and
- 14 scientists released a letter today which was
- 15 submitted to the docket, raising alarm about the
- 16 rule and the harms that it would bring about.
- In the letter, they say as scientists and
- 18 health professionals we recognize the importance
- of data sharing and replicability in scientific
- 20 practice and discourse. The experts are part of
- 21 Project Tender, and their letter is also publicly
- 22 available.

- 1 They say the proposed rule is about
- 2 stiffing science used by EPA, not improving it.
- 3 They all have careers devoted to protecting
- 4 children and their families from exposures to
- 5 neurotoxic chemicals. They say the proposal could
- 6 also undercut existing safeguards. Regulations
- 7 that have led to protections against toxic air
- 8 pollution, lead and drinking water, and dangerous
- 9 pesticides, such as chlorpyrifos.
- Dr. Phil Landrigan, a globally renowned
- 11 expert on childhood harm from chemical pollutants
- warned that if you implement this proposed rule
- the inevitable consequence is that chemicals with
- 14 potential to damage children's brains and nervous
- 15 systems will remain longer on the market, and many
- thousands of children born, and not yet born, who
- 17 could have been protected against these chemicals,
- 18 will be unnecessarily exposed. Brain damage with
- 19 loss of intelligence, disruption of behavior, and
- 20 diminished lifetime achievement will be the
- 21 result. Is this the legacy that EPA wishes to
- 22 leave for America's children?

- 1 The Economist also wrote about the rule,
- 2 very bluntly in an article titled, "Swamp science:
- 3 Scott Pruitt embarks on a campaign to stifle
- 4 science at the EPA." In that Economist article
- 5 they emphasized that the proposal rule is really
- 6 about blocking information used by EPA to protect
- 7 our health. The rule prohibits the Agency from
- 8 setting regulations that are supported in part or
- 9 whole by data that is not publicly available for
- 10 reanalysis or that cannot be replicated. It will
- 11 hamstring EPA's use of scientific information,
- which could only harm EPA's work quality and
- 13 public credibility.
- There are many reasons why a study cannot
- 15 be made fully public or replicated. For example,
- 16 the original raw data may no longer be -- exist.
- 17 Or the original exposure conditions may no longer
- 18 exist, such as lead exposures from leaded
- 19 gasoline, and patient protection and privacy rules
- 20 may prevent full disclosure of the raw data, or
- information. EPA already has long-established and
- transparent methods for evaluating data in these

- 1 situations.
- This rule would block the studies used to
- 3 set air pollution regulations that will have
- 4 prevented more than 30,000 premature deaths by
- 5 2020, with benefits valued at 30 times the cost of
- 6 the Clean Air Act, according to EPA scientists and
- 7 technical experts.
- The rule would also block the studies
- 9 that protect children from lead poisoning in air,
- 10 water, and soil, and would block the studies of
- 11 harmed children that support an EPA proposed ban
- on the neurotoxic pesticide chlorpyrifos, which
- 13 President Trump and former Administrator Pruitt
- 14 have already rolled back those proposals.
- This may be the most unpopular proposal
- 16 from an already unpopular EPA administration to
- 17 date. It is a rule that fundamentally purports to
- 18 solve a problem that doesn't exist, and it should
- 19 be abandoned. It cannot be fixed. Thank you.
- MR. ROBBINS: Thank you.
- MR. MILLER: Hello. My name is Paul
- 22 Miller. It's M-I-L-E-R. I am Deputy Director

- 1 of the Northeast States for Coordinated Air Use
- 2 Management, or NSCAUM. NSCAUM is the regional
- 3 association of state air agency air quality
- 4 control agencies in Connecticut, Maine,
- 5 Massachusetts, New Hampshire, New Jersey, New
- 6 York, Rhode Island, and Vermont.
- 7 My comments today reflect the majority
- 8 view of NSCAUM's members, while individual members
- 9 may hold some views different from the majority
- 10 consensus.
- In sum, we are concerned that should this
- 12 proposal lead EPA to not fully consider the best
- 13 available science in rulemakings, it will endanger
- 14 public health and the environment.
- The EPA invokes strengthening
- 16 transparency as a primary driver for this
- 17 proposal, but fails to describe how a perceived
- 18 lack of transparency has hampered past
- 19 rulemakings. It provides no examples of work,
- 20 quote, "EPA has not previously implemented these
- 21 policies and guidance in a robust and consistent
- 22 manner," end quote, nor what are the specific

- 1 quote, "Agency culture and practices regarding
- 2 data access, " end quote. That requires changing.
- The Agency also provides no cost analysis
- 4 of this proposal. Without additional clarity from
- 5 EPA we are having difficultly identifying the
- 6 problem EPA seeks to address. Therefore, for the
- 7 following reasons we request that EPA withdraw the
- 8 proposed rule.
- 9 First, the proposal is too vaque as
- written to provide the public with meaningful
- opportunity to comment. EPA solicits comments
- 12 across a long list of topic areas, but fails to
- 13 provide the Agency's own sufficient detail and
- 14 rationale on the solicited comment areas as
- 15 required by the Administrative Procedure Act.
- We are left to speculate on EPA's views,
- 17 and on those of other commenters that would
- 18 presumably shape EPA's final rule. It is well
- 19 settled law that this approach fails to provide
- 20 adequate notice for informed public comment.
- Second, EPA must describe how the
- proposed text in Sections 30.5, 30.7, and 30.9

- 1 affect current practice. Section 30.5 states that
- 2 the Agency shall ensure that those response data
- 3 and models underlying pivotal regulatory science
- 4 are publicly available in a manner sufficient for
- 5 independent validation.
- 6 Section 30.7 states, EPA shall conduct
- 7 independent peer review on all pivotal regulatory
- 8 science used to justify regulatory decisions.
- 9 EPA, however, does not describe what constitutes
- 10 in its view, independent validation and
- independent peer review.
- Furthermore, Section 30.5 includes
- 13 qualifying language that EPA will take all
- 14 reasonable efforts to make data available unless
- it is not possible due to other constraints, such
- 16 as legal protections of privacy and
- 17 confidentiality.
- EPA provides no examples of where and
- 19 how, in the Agency's view, past rulemaking
- 20 specifically failed to make these same efforts,
- 21 nor how EPA would change past practice in this
- 22 context. Adding to the vagueness of Sections 30.5

- 1 and 30.7, Section 30.9 would provide the
- administrator with broad authority to exempt
- 3 regulatory decisions from the proposed disclosure
- 4 provisions on a case-by-case basis if he or she
- 5 determines that compliance is impracticable. The
- 6 proposed rule fails to provide specific criteria
- 7 for determining when compliance is impracticable.
- 8 Lacking clear guidelines for transparent
- 9 decision-making, the administrator's discretion
- 10 would appear to be unbounded in application and
- 11 potentially based on haphazard and non-transparent
- 12 rationales.
- Third, EPA has provided no meaningful
- 14 cost estimate for the proposed rule. The costs
- 15 are likely quite significant, however, based on a
- 16 congressional budget office cost estimate of the
- 17 similar congressional proposal.
- In addition to lack of cost information,
- 19 EPA offers no accounting of foregone benefits
- 20 should a broad application of this proposal limit
- the use of the best available science in setting
- 22 public health standards and preventing adverse

- 1 health outcomes.
- In conclusion, EPA's proposal has far-
- 3 reaching consequences on the future use of science
- 4 by the agency. These consequences, however
- 5 significant they may be, are indeterminate in
- 6 light of the proposal's vagueness. The proposal
- 7 fails to clearly articulate the problem EPA seeks
- 8 to address, the specific proposed rule
- 9 requirements, and its cost and benefits.
- These are well understood and basic
- 11 elements that federal agencies must include to
- 12 ensure informed public comment. Given that these
- 13 elements are missing from this proposed, EPA
- 14 should withdraw it. Thank you.
- MR. ROBBINS: Thank you.
- MS. HALL: Would Speaker Number 30,
- 17 Matthew McKinzie and Speaker Number 31, Anne
- 18 Mellinger-Bird (sic) come to the speaker's table.
- 19 Would Speaker Number 32, Erica Bardwell, and
- 20 Speaker Number 33, Jennifer Reaves, take a seat at
- 21 the on-deck chair.
- MR. McKINZIE: Good morning. I'm Matthew

- 1 McKinzie, M-C-K-I-N-Z-I-E. I'm a nuclear
- 2 physicist with the Natural Resources Defense
- 3 Council, NRDC, and I'm very pleased to talk today
- 4 about this proposed rule. My remarks will focus
- 5 in on the radiation protection aspect of the
- 6 proposed rule.
- 7 NRDC, just as background, is a national
- 8 non-profit organization of scientists, lawyers,
- 9 and environmental specialists. We are dedicated
- 10 to protecting the public health and the
- 11 environment.
- NRDC has been engaged with the
- 13 environmental issues surrounding nuclear energy
- 14 and nuclear weapons since our founding. There's
- 15 something strange about the proposed rule in that
- 16 it does not use the word radiation, and it does
- not cite the EPA's authority under the Atomic
- 18 Energy Act.
- Nevertheless, the language of the
- 20 proposed rule seems to clearly implicate radiation
- 21 protection standards. In particular, appears to
- undermine the basis, a fundamental basis of

- 1 radiation protection standards, the linear no-
- threshold dose response model. And so that's what
- 3 I'll focus on with my five minutes.
- 4 The science in radiation epidemiological
- 5 studies has repeatedly demonstrated over decades
- 6 that linear no-threshold dose response, LNT,
- 7 provides the most reasonable description of the
- 8 relation between the low dose, low radiation dose
- 9 exposure, and the incidence of solid cancers that
- 10 are induced by that ionizing radiation.
- 11 EPA bases its regulatory limits and
- nonregulatory guidelines for population exposure
- to low-level ionizing radiation on this linear no
- 14 threshold model. EPA's radiation protection
- 15 standards are based on the premise that any
- 16 radiation does carries some risk, and that risk
- increases directly with dose.
- This method of estimating risk is called
- 19 LNT. For over 40 years, the LNT dose response
- 20 model has been commonly utilized when developing
- 21 practical and prudent guidance on ways to protect
- workers and members of the public from the

- 1 potential for harmful effects from radiation in
- that balance, with commercially justified and
- 3 optimized uses of radiation. EPA derives the LNT
- 4 model from reports by authoritative scientific
- 5 bodies, including the National Academy of
- 6 Sciences, NAS, the National Council on Radiation
- 7 Protection and Measurements, NCRP, and other
- 8 bodies.
- 9 The NCRP published its last commentary on
- the LNT issue only weeks ago, in April of 2018,
- 11 reinforcing this -- the LNT as the basis for
- 12 radiation protection standards.
- Epidemiological studies of humans provide
- 14 evidence that is critically important in
- 15 establishing potentially causal associations of
- 16 environmental factors with disease. NAS and other
- 17 studies that EPA has long relied upon in the
- 18 radiation standard setting process are
- 19 epidemiological human cohort studies. EPA's
- 20 proposed rule, if implemented, would limit EPA
- 21 staff from basing regulatory actions on precisely
- these types of studies by requiring that the

- 1 underlying data of these studies should be
- publicly shared, fully publicly shared. This
- 3 would be a nearly impossible task for the agency.
- 4 Data for some of the radiation
- 5 epidemiological studies are accessible to users,
- 6 with a detailed description of how a user can
- 7 access the information. However, public sharing
- 8 of personally identifiable information is
- 9 restricted. These are profoundly important
- 10 studies on radiation health effects that have been
- 11 peer reviewed for decades, and the science that
- 12 has emerged from them has been validated multiple
- 13 times. But these are not studies where the
- 14 entirety of the public data can be shared or
- independently replicated.
- Replication of these studies is
- 17 impossible as this data comes from individuals
- 18 exposed to significant, acute, and protracted
- 19 doses of radiation. Pruitt's proposed rule would
- 20 throw out the data from the atomic bomb survivors
- of World War II. That's a profound, very profound
- 22 thing.

- 1 Adverse consequences for EPA would affect
- 2 federal guidance reports, nuclear field cycle
- 3 standards and regulations, minimum amount --
- 4 minimum allowed concentrations of radiation in
- 5 drinking water, soil clean up for super fund
- 6 sites, radioactive waste disposals, as well as the
- 7 fundamental concept of ALARA, As Low As Reasonably
- 8 Achievable, in radiation protection standards.
- In conclusion, I urge the EPA to abandon
- 10 the proposed rule as it fundamentally calls into
- 11 question basic radiation protection standards that
- are scientifically founded and have protected the
- 13 public for many years. Thank you.
- MR. ROBBINS: Thank you.
- MS. MELLINGER-BIRDSONG: Hi. My name is
- 16 Anne Mellinger-Birdsong, M-E-L-L-I-N-G-E-R, dash,
- B-I-R-D-S-O-N-G.
- Thank you for allowing me to speak today.
- 19 My name is Anne Mellinger-Birdsong, and I am a
- 20 fellow of the American Academy of Pediatrics and a
- 21 specialist in environmental public health. I have
- worked at city, county, state, and federal public

- 1 health agencies, and Indian health service
- 2 facilities.
- I'm here to speak in opposition to this
- 4 proposed rule and to state that this proposed rule
- 5 is unnecessary and it would harm EPA's ability to
- 6 evaluate health impacts of environmental
- 7 pollutants. It should not be finalized or
- 8 implemented.
- 9 This proposal has wording that makes it
- 10 appear noble and well-meaning, but it is a sheep
- in wolf's clothing. This proposal will severely
- 12 hamper EPA's ability to use past and future
- 13 research on health effects of human exposure to
- 14 environmental chemicals and toxicants. It should
- 15 be withdrawn.
- Both the HIPAA and the federal
- 17 regulations on human subjects research address
- 18 privacy as a concern of people who participate in
- 19 research. It's not as simple as redacting data
- 20 such as name, birth date, medical record number,
- 21 et cetera. You also have to not have data that
- can be used to intuit or figure out who a study

- 1 subject is. So you have a study of Town A and
- people who had heart attacks in July. If there is
- 3 age or zip code data associated with that, the
- 4 people that live in Town A could figure out, oh,
- 5 that's Mr. X down the street. So it would really
- 6 hamper the ability to use data, and environmental
- 7 health data often has zip code and year and a lot
- 8 of stuff that can be used to put together and
- 9 figure out who people are.
- So that's how it would work. And I just
- would like to say also that children have even
- more health protections than adults because of
- 13 being smaller, and we have to be more concerned
- 14 for them. And especially living human subjects of
- 15 research who will continue to live, we need to be
- 16 extra careful to protect their privacy. And this
- 17 rule would either require data made public, or it
- 18 would prohibit using a lot of data that would
- 19 enable -- that would inhibit privacy protection.
- So also it would decrease people's trust
- in participating in research if they are fearful
- of their personal identifiers being released or

- 1 people being able to know that they participated
- 2 in a study. They may not participate, so we would
- 3 have worse data for studies in the future because
- 4 of this rule.
- And I would like to say that children do
- 6 not choose where they live, or where they go to
- 7 school, or what kind of water quality their water
- 8 they drink is, or the air that they breathe. It's
- 9 up to we, who are adults, the adults who are their
- 10 caretakers who choose where they live, and we who
- 11 set policies to make these decisions to keep
- children healthy. And this rule would severely
- 13 harm children because it will throw out a lot of
- 14 data, and a lot of data that has been used to
- 15 form, already, established rules.
- So I ask, why was this rule proposed? It
- 17 would eliminate use of scientific studies and
- 18 hamper future research. The rule was completely
- 19 unnecessary. We have mechanisms within scientific
- 20 institutions to transfer data so it's HIPAA
- 21 compliant and IRB approved, so we can verify
- 22 research and reevaluate it and confirm it. We

- 1 don't need this rule and it is, again, it's a rule
- 2 that's unnecessary and would hamper and harm EPA's
- 3 ability to carry out its functions.
- So I'm going to end with a quote by a
- 5 professor from Carnegie Mellon University, Granger
- 6 Morgan. He used to chair the EPA Science Advisory
- 7 Board under George W. Bush. He said, "this
- 8 proposed rule is an attempt by people who aren't
- 9 interested in using science to find the truth to
- 10 raise doubts about what, at this stage, is very
- 11 clearly established and well-reviewed science."
- And I urge the EPA to withdraw this
- 13 proposed rule and not implement it at all.
- MR. ROBBINS: Thank you.
- MS. HALL: Would Speaker Number 32, Erica
- 16 Bardwell, and Speaker Number 33, Jennifer Rebeb
- 17 (sic), come up to the speaker's table. And
- 18 Speaker Number 34, Molly Rauch, and Speaker Number
- 19 35, Barbara Gottlieb, take a seat at the on-deck
- 20 chairs.
- Speakers are reminded to speak into the
- 22 mic and state your organization.

- MS. REAVES: Hi. My name is Jennifer
- 2 Reaves. Reaves spelled R-E-A, V as in Victor, E-
- 3 S. I represent Moms Clean Air Force, Maryland.
- Am I supposed to speak first? Oh, okay.
- 5 My name is Jennifer Reaves. I live in
- 6 Hyattsville, Maryland. Thank you for this
- 7 opportunity to offer comment. As a member of Moms
- 8 Clean Air Force, Maryland, I am here today to
- 9 speak out in opposition to Acting Administrator
- 10 Andrew Wheeler's attempts to censor science in the
- 11 name of transparency.
- 12 This dangerous censoring sign plan to
- 13 limit the scientific information EPA can use to
- 14 identify public health threatens and future and
- 15 safety of our children. This proposal will
- 16 essentially require researchers to make private
- 17 personal medical information public in order for
- 18 the EPA to use their research in its decision-
- 19 making.
- This proposal also includes loop holes
- that would exempt industry from having to disclose
- 22 details of their own studies. It is designed to

- 1 favor the fossil fuel and chemical industries,
- 2 limiting EPA's ability to protect us from toxic
- 3 pollution and chemicals. High quality science is
- 4 crucial to understanding the risk of our families
- 5 face every day, especially when it comes to air
- 6 pollution and toxic chemical exposure.
- 7 This proposal means that many studies on
- 8 populations, such as elderly, young people, and
- 9 people of color, groups who are often suffer
- 10 disproportionately from pollution would be
- 11 excluded from EPA consideration because making the
- 12 data public could identify and participating --
- 13 identify the participating individuals. Including
- 14 this important data from consideration means that
- implementing this proposal could even further
- 16 exuberate negative environmental impacts on these
- 17 and other vulnerable communities.
- This proposal puts our children's bodies
- on the line by censoring research, making even low
- 20 levels of pollution with significant health
- impacts instead of cleaning up their act.
- 22 Polluting industries want these kind of studies to

- simply disappear.
- 2 My family and my fellow Marylanders are
- 3 counting on the sound and transparent science the
- 4 EPA has used for decades. And we are counting on
- 5 our medical records remaining private. I strongly
- 6 urge the EPA to stop this radical proposal for the
- 7 health and safety of all Americans. Thank you.
- MR. ROBBINS: Thank you.
- 9 MS. BARDWELL: All right. Excuse me.
- 10 Thank you. My name is Erica Bardwell. Can you
- 11 hear me? Okay.
- I am a local registered nurse. I work at
- a local hospital. I'm also a member of Physicians
- 14 for Social Responsibility. Thanks for taking time
- 15 today.
- Mr. Scott Pruitt is no longer here as EPA
- 17 administrator, but it does seem that this proposal
- 18 preserves the hallmark of his tenure. By that I
- 19 have to say, I mean a complete lack of shame.
- This proposal masquerades as an attempt
- to strengthen science, and by extension, public
- 22 health. But this is a bald, even shameless lie.

- 1 It would actually make public health research
- 2 impossible, or much, much more difficult, which
- 3 obviously is the real point.
- If someone can't participate in medical
- 5 research without worrying that their identities or
- 6 parts of their medical records are going to be
- 7 rampaging around the public record, then they
- 8 simply won't do it. Which again, is the point.
- 9 Basically, shameless people say that to
- 10 themselves behind their scenes. But to us they
- 11 say that they're really concerned about us and
- 12 public transparency, but it's not true.
- I saw a reference to a replication
- 14 crisis. Last I heard, the replication crisis was
- 15 mostly social sciences. There's not a huge
- 16 replication crisis in epidemiology. Certainly not
- 17 to the point where basic facts are in doubt.
- 18 There is no doubt that air pollution kills people,
- 19 that poison in water makes people sick, that toxic
- 20 soil grows toxic food. This is not in contention.
- 21 There's no replication crisis here.
- So the only purpose of this rule could be

- 1 to avoid adding to the already damning weight of
- 2 this existing evidence. Basically, to make it
- 3 cheaper for a few people to literally poison
- 4 people for profit, which is ultimately a tragedy
- 5 for everybody.
- I think the thinking is that sciencing
- 7 debates are going to bore the public, and most
- 8 other people have to work on a random Tuesday. I
- 9 swapped a shift to be here, but most people don't
- 10 have that option.
- MS. DOA: Can you speak into the mic a
- 12 little bit more?
- MS. BARDWELL: Sure. Okay.
- MS. DOA: That's better. Thank you.
- MS. BARDWELL: So, the true public
- interest may not be represented here because
- 17 people have to work. But if this rule is
- 18 finalized, the public is going to howl once they
- 19 actually feel its effects and lose the protection
- 20 that they need from these studies. And I wouldn't
- want to be the person left holding the bag when
- 22 that travesty happens.

- Finally, as my grandmother used to say,
- what sauce is for the goose is sauce for the
- 3 gander. If exposing personal information is
- 4 really required to have quality medical research,
- 5 I eagerly await the day this administration
- 6 proposes similar restrictions on, say,
- 7 pharmaceutical research. I wait for the day that
- 8 Pfizer can't get approval for its nth blood sugar
- 9 pill without revealing incredibly invasive
- information about all of its research subjects. I
- don't think that day is ever going to come,
- 12 because protecting people or advancing science
- isn't really the goal.
- Thanks for your time.
- MR. ROBBINS: Thank you.
- MS. HALL: Would Speaker Number 34, Molly
- 17 Rauch, and Speaker Number 35, Barbara Gottlieb
- 18 come to the speaker's table. And Speaker Number
- 19 36, Lyndsay Alexander, and Speaker Number -- is
- there a Speaker Number 37 in the room? What's
- your name?
- MS. BENDER: Laura Bender.

- MS. RAUCH: Hi. I'm Molly Rauch. Name
- 2 is spelled M-O-L-L-Y R-A-U-C-H. I'm Public Health
- 3 Policy Director with Moms Clean Air Force. We're
- 4 a national organization of more than a million
- 5 moms and dads fighting air pollution and climate
- 6 change for the sake of our children's health.
- 7 Thanks for this opportunity to offer
- 8 comment. On behalf of our more than 1 million
- 9 members, I am here today to strongly oppose the
- 10 administration's attempts to censor the science
- used in public health decision-making. This
- intentionally misleading proposal is being sold by
- 13 EPA leadership as an effort to increase
- 14 transparency. But the facts suggest that the real
- motivation is simply to sweep under the rug the
- 16 scientific evidence disfavored by polluting
- 17 companies.
- The proposal would prevent EPA from using
- 19 studies that are based on personal medical data,
- 20 thereby eliminating some of the most important
- 21 long-term epidemiological studies, investigating
- the impacts of pollution on public health, and

- 1 hundreds of scientists have already spoken out
- 2 against this proposal.
- Indeed, this flimsy proposal was designed
- 4 without adequate input from the scientific
- 5 community, according to the members of EPA's own
- 6 Scientific Advisory Board. It was rushed through
- 7 the regulatory process. It was originally
- 8 proposed with a gallingly short public comment
- 9 period that suggested an intention of casting less
- 10 light on the rulemaking process, not more.
- 11 For a proposal that posits a sweeping
- 12 change in the health-based rulemaking that is the
- 13 foundation of the EPA, it was quite the slight of
- 14 hand.
- As a public health expert who has been
- 16 closely following EPA's rulemaking process for
- more than a decade, it is evident to me that this
- is a cynical ploy to bolster polluting industries
- that don't like the results of longitudinal
- 20 research.
- Who does this benefit? Who really
- 22 benefits from this charade? I must call it a

- 1 charade. Not the families everywhere who want to
- 2 breathe clean air and drink clean water. Not
- 3 frontline communities dealing with multiple
- 4 pollution exposures from many industrial sources.
- 5 Not the millions of children in the U.S. with
- 6 asthma across the country whose disease can be
- 7 worsened by small changes in air quality day to
- 8 day, not the elderly, not those with underlying
- 9 health problems whose likelihood of being admitted
- 10 to the hospital, of having a stroke, of having a
- 11 heart attack, even of dying, could depend on the
- 12 levels of particulate pollution in the air. It
- does not benefit these people.
- I have a master's degree in public
- 15 health. One of the most valuable things that I
- 16 studied in graduate school was how to evaluate the
- 17 reliability of epidemiological studies. We learn
- 18 the importance of considering many different
- 19 criteria in making these evaluations. Whether the
- 20 raw data was available to me, personally, to
- 21 review, was never grounds for automatically
- 22 discounting the credibility or reliability of any

- ı given study.
- The idea that an entire library of
- 3 research would be rejected wholesale, based simply
- 4 on that one external criteria, represents a crude
- 5 approach, to put it kindly.
- We also, in grad school, learned about
- 7 the iron-clad importance of treating study
- 8 subjects ethically and with respect. And this is
- 9 a touchstone of public health practice. All
- 10 research on humans must be approved by
- institutional review boards, and they prioritize
- 12 the privacy and consent of study subjects. There
- 13 are laws about this.
- When study subjects are disrespected
- 15 terrible things can happen, which is why we were
- 16 required to learn about things like the, "Tuskegee
- 17 Study of Untreated Syphilis in African/American
- 18 (sic) Men," when we were in public health school.
- 19 We cannot go back to the time when the study
- 20 subject was a mere pawn in someone else's game.
- 21 Treating study subjects ethically requires
- 22 protecting their privacy.

- Finally, we studied the tactics of
- polluting industries and their shameful legacy of
- attempting undermine science, whether it was the
- 4 tobacco industry or the lead industry, we learned
- 5 about the deliberate, expensive, decades-long
- 6 campaigns to protect corporate profits, and
- 7 meanwhile people were literally dying as a result.
- 8 This is an old story. We've heard it before, and
- 9 we're hearing that story again. Public health
- 10 professionals are trained to recognize history and
- 11 call it out, which is what we are doing today.
- This proposal is an excuse to hamstring
- 13 researchers to weaken public health protections,
- 14 and to pad the profits of polluting industries.
- 15 As a public health professional, as a mother, and
- on behalf of the 1 million members of Moms Clean
- 17 Air Force, I strongly urge the EPA to stop this
- 18 proposal for the health and safety of all
- 19 Americans. Thank you.
- MR. TEICHMAN: Thank you.
- MS. GOTTLIEB: Good morning. My name is
- 22 Barbara Gottlieb, G-O-T-T-L-I-E-B. I'm the

- 1 Director for Environment and Health at Physicians
- 2 for Social Responsibility.
- On behalf of our 33 members, I'm here to
- 4 express our opposition to the proposed rule --
- 5 "Strengthening Transparency in Regulatory
- 6 Science."
- 7 The U.S. EPA plays a critical role in
- 8 keeping our nation and our families safe from
- 9 environmental exposures that can cause illness and
- 10 death. We thank you for that and we count on you
- 11 for it. Because your role is vital to our health
- and well-being, the nation relies on you to
- 13 formulate and enforce the most effective
- 14 protections possible, based on the best available
- 15 science. The medical and scientific studies that
- underlie the EPA's decisions must be objective,
- 17 vetted, and present a full and accurate assessment
- of the threats to health posed by the pollutants
- 19 under study.
- To provide those full and accurate
- 21 assessments, studies need to relate exposure
- levels to actual health outcomes in real human

- 1 beings, and to amass large data bases so that
- 2 researchers can draw valid conclusions.
- In order to have reliable data and large
- 4 sample sizes, researchers frequently study the
- 5 records of patients treated in hospitals. Hospital
- 6 records, of course, include personal identifiers,
- 7 and disclosure of those identifiers would violate
- 8 privacy and confidentiality laws. Thus, the best
- 9 available data for many health studies cannot be -
- in the literal sense -fully and openly shared.
- However, to refuse to consider scientific
- 12 studies simply because they include personal
- identifiers -- would be a great mistake, nor is it
- 14 necessary. Reviewers wanting to reproduce a study
- in order to validate it can arrange to have
- 16 confidential access to key data. Furthermore,
- 17 scientists can assess the merits of published
- 18 research without seeing its data by considering
- 19 such published features as the study's research
- 20 design, the methods used for data collection and
- 21 analysis, and comparison with previous results.
- In any case, to exclude credible peer-

- 1 reviewed scientific studies because the personal
- 2 identifiers cannot be released under the law, is
- 3 to exclude from the EPA's consideration many
- 4 important and valid studies. This would greatly
- 5 hamper our ability, your ability, to understand
- 6 the impacts of serious, even deadly, pollutants.
- 7 I'd like to cite, as example, three
- 8 studies that could be lost to consideration under
- 9 the proposed rule, on a topic I haven't heard
- 10 referred to today. These studies reveal
- 11 statistical correlations between exposure to
- 12 emissions from fracturing, or fracking, for oil
- 13 and gas, and serious health outcomes.
- So the first is a study by University of
- 15 Pennsylvania and Columbia University researchers
- and published in 2015 in the journal, PLoS ONE,
- 17 found that drilling and fracking activity in
- 18 Pennsylvania was associated with increased rates
- of hospitalization for cardiology, neurology,
- 20 cancer, skin conditions, and urological problems.
- In communities with the most wells, the
- rate of cardiology hospitalizations was 27 percent

- 1 higher than in control communities with no
- 2 fracking. These findings are obviously of great
- 3 concern; we would not want them to be lost to the
- 4 EPA as you consider regulation of fracking related
- 5 emissions.
- Yet because the data includes such things
- 7 as patients' names, diagnoses, addresses, and zip
- 8 codes, this valuable study could be, under the
- 9 proposed rule, excluded from EPA consideration.
- 10 Another study conducted in Pennsylvania
- 11 between 2005 and 2012, found that living near
- 12 fracking operations significantly increases asthma
- 13 attacks. This study was conducted by researchers
- 14 at Johns Hopkins University and it was based on a
- 15 study of 35,000 medical records of people with
- 16 asthma. This is just the sort of study that we
- 17 want EPA to base its health-protective regulations
- on: a robust database conducted by researchers at
- 19 a respected institution and published, as this one
- 20 was, in the Journal of the American Medical
- 21 Association Internal Medicine.
- Yet should the proposed rule be adopted,

- 1 this study could be disallowed because its 35,000
- 2 medical records cannot easily be scrubbed of
- 3 personal identifiers.
- Third example, a study by the Johns
- 5 Hopkins Bloomberg School of Public Health and
- 6 other researchers, used data from the Geisinger
- 7 Health System on over 9,000 pregnant women and
- 8 their over 10,000 newborns between January 2009
- 9 and January 2013. The researchers found that the
- 10 pregnant women who live near active fracking
- operations in Pennsylvania were at a 40 percent
- increased risk of giving birth prematurely.
- 13 Premature birth is the leading cause of infant
- 14 death in this country.
- So we're talking about data that indicate
- 16 that fracking operations could put newborn babies
- 17 at risk of death. This was a study published in
- 18 the peer review journal, Epidemiology.
- Our families should have the benefit of
- 20 these studies and many more that might be
- 21 disregarded under the proposed rule. To exclude
- them would be to weaken the scientific record and

- 1 undercut an accuracy and strength of EPA's
- regulatory process, and to endanger human health.
- For that reason, Physicians for Social
- 4 Responsibility opposes the proposed rule. Thank
- 5 you.
- 6 MR. ROBBINS: Thank you.
- MS. HALL: Would Speaker Number 36,
- 8 Lyndsay Alexander, and Speaker Number 37, Laura
- 9 Bender, come up to the speaker's table.
- And would Speaker Number 38, Liz
- 11 Borkowski, and Speaker Number 39, Janice Nolen,
- 12 take your seat at the on-deck chairs.
- MS. ALEXANDER: Good morning. My name is
- 14 Lyndsay Alexander, A-L-E-X-A-N-D-E-R. I direct
- 15 the National Health Year Campaign at the American
- 16 Lung Association. I am also the mother of a
- 17 thriving toddler, who like all children, deserves
- 18 healthy air to breath, and safe water to drink
- 19 that won't make him sick or die prematurely.
- I am here to ask EPA to withdraw this
- 21 proposed rule because I'm very concerned that
- 22 rather than foster transparency in regulatory

- 1 science, this rule promotes a callous effort to
- 2 suppress and censor the science used to inform EPA
- 3 policy to the detriment of millions of Americans'
- 4 health and well-being.
- 5 EPA's ability to effectively fulfill its
- 6 mission and protect public health from dangers,
- 7 such as air pollution, hinges on the ability of
- 8 its scientists to first evaluate the best
- 9 available scientific evidence of the health
- 10 threats of air pollution. Recognizing that
- 11 scientists' understanding of the relationship
- between air pollution and public health would
- continue to evolve, congress wisely required EPA
- 14 to review the latest evidence and revise air
- 15 pollution limits for six key pollutants every five
- 16 years. And then to work with states to reduce
- 17 pollution to meet the limit.
- While more work remains, this basic
- 19 approach has worked exceedingly well at reducing
- 20 ambient air pollution, saving lives, and improving
- 21 health by preventing asthma attacks, heart
- 22 attacks, and many other negative health outcomes

- 1 from air pollution.
- This proposed rule would require EPA to
- 3 exclude many of the best available peer-reviewed
- 4 and rigorously scrutinized studies from
- 5 consideration during decision-making, such as its
- 6 upcoming air quality standard reviews for ozone
- 7 and particulate matter.
- 8 Excluding studies for which raw data are
- 9 not available due to concerns over patient
- 10 confidentiality, or which do not meet vague
- 11 standard of reproducibility because studies were
- conducted over long periods of time, or connected
- 13 to real world events beyond the control of
- 14 researchers, would greatly narrow the body of
- 15 evidence and the quality of the information that
- 16 EPA can consider. This would undoubtedly lead to
- weaker protections and EPA's ability to estimate
- 18 the true threats of air pollution on human health,
- 19 and the benefits of reducing pollution, and thus
- 20 result in weaker air pollution limits.
- In 1993, researchers at Harvard
- 22 University published a landmark air pollution

- 1 study, showing that particulate matter air
- 2 pollution was linked to premature death. The
- 3 Harvard Six Cities Study, as it is known, tracked
- 4 the health of 8,111 adults, and 14,000 children in
- 5 six small cities in the United States, beginning
- 6 in the 1970s.
- 7 This study found that people in cities
- 8 with cleaner air were living two to three years
- 9 longer than those living in cities with dirtier
- 10 air. Residents of Steubenville, Ohio, the city
- 11 with the dirtiest air, were 26 percent more likely
- to die prematurely than were citizens of Portage,
- 13 Wisconsin, the city with the cleanest air.
- What surprised researchers was that the
- 15 culprit was particulate matter, not sulfur-
- 16 dioxide, as they had thought. This was a very
- 17 important scientific discovery. This study, and
- 18 countless others since, have helped EPA to
- 19 understand that particle pollution in the air we
- 20 breathe, resulting from activities such as burning
- 21 coal for electricity, or diesel exhaust from
- vehicles, harms human health in profound ways in

- 1 communities across the nation and has paved the
- 2 way for stronger air pollution limits designed to
- 3 protect public health.
- But the data for the Harvard Six Cities
- 5 Study are not publicly available, and the study
- 6 was conducted over a long period of time that make
- 7 it very difficult to reproduce. Industry, and
- 8 their allies in congress previously challenged the
- 9 findings of this study and other similarly
- 10 important studies. Instead of blocking the
- 11 studies, as this proposal would do, EPA took a
- 12 logical step and referred them to an independent
- third-party, the Health Effects Institute, for a
- 14 deep dive review.
- There, autonomous reviewers examined the
- 16 data and developed a report that confirmed their
- 17 original findings. Other research has since
- 18 confirmed similar findings, including some studies
- 19 that use publicly available data sets. Critically
- 20 important studies, such as the Harvard Six Cities
- 21 Study would likely be excluded under this proposal
- 22 to the detriment of health protections. This

- 1 proposal would also affect other protections
- 2 currently in place, such as limits on certain
- 3 toxic air emissions from tail pipes and smoke
- 4 stacks, and information on the health effects of
- 5 many of these; more than 150 chemicals come from
- 6 older studies built on confidential patient or
- 7 private business data that cannot be made public.
- 8 This could -- this proposal could also
- 9 cull the use of research that includes
- 10 confidential business information or older studies
- 11 that has data stored on older technology that
- can't be recovered, just to name two other
- 13 limitations.
- Thank you for the opportunity to speak
- 15 today. The American Lung Association will submit
- 16 more detailed written comments.
- MR. ROBBINS: Thank you.
- MS. BENDER: Good morning. My name is
- 19 Laura Bender, L-A-U-R-A B-E-N-D-E-R, and I'm the
- 20 National Director of Advocacy of the American Lung
- 21 Association's Healthy Air Campaign.
- The lung association's mission is to save

- 1 lives by improving lung health and preventing lung
- 2 disease. And as you know, we strongly oppose
- 3 EPA's so-called, "Strengthening Transparency in
- 4 Regulatory Science," proposal.
- 5 Today you've heard from many
- 6 representatives at the public health and medical
- 7 community about the ways this proposal would
- 8 undermine human health. I'd like to take a few
- 9 minutes to highlight the Lung Association's
- 10 concerns about the lack of transparency in EPA's
- 11 work on this rule.
- The administration has attempted to rush
- this rule forward at every turn, consistently
- 14 sacrificing expert analysis and public health
- 15 along the way. This is a sweeping proposal that
- 16 will impact a wide range of public health
- 17 safeguards, essentially affecting every future
- 18 decision at EPA based on science. And yet, EPA's
- 19 process in issuing it has been haphazard, rushed,
- 20 and anything but transparent.
- 21 First, back in April, then Administrator
- 22 Scott Pruitt, prematurely announced the proposal

- while it was still undergoing interagency review
- 2 at the White House Office of Management and
- 3 Budget. Then, when media inquired about this
- 4 discrepancy, OMB actually backdated the clearance
- 5 by several days. This means that OMB only
- 6 reviewed the proposal for 48 hours. That's a
- 7 staggering tight timeline for such a sweeping
- 8 rule.
- In a similar vein, EPA initially only
- 10 allowed a 30-day comment period with no public
- 11 hearing. The Lung Association was among the
- organizations who requested 60 additional days and
- 13 a hearing. We greatly appreciate the additional
- 14 time and today's public hearing.
- That additional time is crucial,
- 16 particularly because EPA has failed to complete a
- 17 regulatory impact analysis that explains the
- 18 impacts of the proposal, putting the burden on
- 19 commenters to do so instead.
- EPA ignored another important opportunity
- 21 for review when it failed to consult the Agency's
- own Science Advisory Board. The SAB, which

- 1 includes appointed members from this
- 2 administration, voted at its May meeting to
- 3 request to review the proposal.
- In a letter to EPA last month, they said
- 5 that they were only made aware of the rule through
- 6 the press, and when it was published in the
- 7 Federal Register. The SAB said unequivocally,
- 8 quote, "The proposed rule merits review by the
- 9 Board."
- We strongly encourage the Agency to move
- 11 forward with the SAB review of the proposal. To
- 12 refuse their request to do so would be
- unprecedented and in direct contradiction of the
- 14 Agency's stated claim of wanting the best science
- 15 to inform its decision-making.
- 16 EPA rushed out this proposal after an
- 17 inadequate review process, and it shows. The
- 18 proposal falls short in several key ways. First,
- 19 EPA fails to provide any evidence that the changes
- 20 outlined in the rule are needed. EPA's existing
- 21 approach towards science, with its detailed review
- 22 and deliberation of the research, is already

- 1 transparent and has worked well for decades.
- First, independent science has revealed
- 3 that studies prior to publication by recognize
- 4 journals, then independent and EPA staff
- 5 scientists reviewed them again and question every
- 6 aspect of the research in depth. And they do
- 7 these reviews in wide open processes, including
- 8 publication, public hearings, and comment periods.
- 9 EPA does not acknowledge the rigor of
- 10 this process in its proposal. Instead, it
- 11 attempts to justify this rule by claiming that the
- 12 Agency is following in the footsteps of scientific
- 13 journals. But last month as other commenters have
- 14 noted, several scientific journals issued a joint
- 15 statement highlighting their concerns with EPA's
- 16 proposal and pointed out that even though many
- 17 peer-reviewed publications have recently adopted
- 18 transparency policies, they are still able to
- 19 assess and use studies for which the underlying
- 20 data cannot be made public.
- Second, EPA fails to define its
- requirement that studies must be replicable. Does

- 1 EPA mean that the Agency couldn't consider a study
- 2 that looked at health impacts of a one-time event,
- 3 like a major oil spill?
- The SAB also raised questions about EPA's
- 5 failure to define this and other terms.
- 6 Finally, EPA did not explain how the
- 7 Agency would implement the rule. The proposal
- 8 offers no process for public hearing, or even
- 9 consultation with the SAB over implementation.
- 10 What process would EPA use to review and assess
- 11 the existing research and revisions? What
- 12 guidance would the administrator receive to avoid
- 13 arbitrary decision-making over the fate of this
- 14 research?
- And where would the massive staff time
- 16 and resources the EPA would need for such a
- 17 massive additional workload come from? What would
- 18 have to be sacrificed?
- EPA's rushed process, its inadequate
- 20 review, its false attempt to claim that its policy
- is supported by scientific journals, and its many
- unanswered questions about how the proposal would

- 1 work, all underscore a core problem with this
- 2 rule. It would not improve the use of science of
- 3 EPA. It would not make the Agency's science-based
- 4 rules more transparent. It would permanently
- 5 damage EPA's ability to do its job to protect the
- 6 public.
- 7 On behalf of the millions of people with
- 8 lung disease that we serve who will be hurt by the
- 9 weaker pollution protections that would result
- 10 from this proposal, we urge EPA to withdraw this
- 11 rule to censor science. Thank you.
- MR. ROBBINS: Thank you.
- MS. HALL: Would Speaker Number 38, Liz
- 14 Borkowski, and Speaker Number 39, Janice Nolen,
- 15 come up to the speaker's table. And Speaker
- Number 40, Albert Donnay, you're already at your
- 17 seat. Excellent. Also, if Speaker Number 15,
- 18 Harvey Fernbach, is in the room, you can take a
- 19 seat at the on-deck chairs. Last call.
- MS. BORKOWSKI: Thank you for the
- 21 opportunity to present comments. My name is Liz
- 22 Borkowski, and I'm the Managing Director of the

- 1 Jacobs Institute of Women's Health, which is at
- 2 the Milken Institute School of Public Health at
- 3 the George Washington University.
- The Jacobs Institute is concerned about
- 5 EPA's proposed rule, "Strengthening Transparency
- 6 in Regulatory Science," due to the harmful impact
- 7 it would have on women's health and reproductive
- 8 justice.
- 9 We urge EPA to withdraw it based both on
- 10 its detrimental impacts, and on the lack of a
- 11 demonstrated need for such a rule. EPA has failed
- 12 to demonstrate that its current processes for
- 13 considering science and regulation are inadequate.
- 14 It has not provided examples of any instances in
- 15 which insufficient transparency has resulted in
- outcomes contrary to its statutory mandates or
- 17 executive orders.
- 18 Given extensive existing procedures used
- 19 by EPA and the scientific community at large to
- 20 ensure the quality of research, EPA has failed to
- 21 make a case that additional public access to data
- 22 is necessary.

- 1 The theoretical, but as yet
- 2 undemonstrated benefits of EPA's proposed rule,
- 3 must be weighed against the extensive and
- 4 unequally distributed costs of such an approach.
- 5 Failing to consider the best available evidence
- 6 because the underlying data are not publicly
- 7 available, would result in regulations that fail
- 8 to sufficiently protect public health. The
- 9 consequences would fall most severely on sensitive
- 10 groups not adequately protected by current rules,
- 11 which include racial and ethnic minorities, those
- with low socio-economic status, the elderly, and
- 13 pregnant individuals and their eventual children.
- My comments provide a few examples
- 15 related to reproductive health. First,
- neurotoxicants are of particular concern to
- 17 pregnant people and the parents of young children.
- 18 In regulatory activities, to reduce exposure to
- neurotoxicants, such as lead and methyl mercury,
- 20 EPA has relied on an extensive body of research.
- 21 This research includes longitudinal studies of
- 22 individuals who are exposed in utero or as young

- 1 children to higher levels of lead or methyl
- 2 mercury than would typically occur in the U.S.
- 3 today. It would not be ethical to publicly
- 4 release data from these studies, and it would not
- 5 be feasible, particularly for older studies that
- 6 used incompatible storage media to locate all
- 7 participants and obtain their permission.
- 8 EPA's use of research on lead and methyl
- 9 mercury also has implications for other agencies
- 10 that address these substances. For instance, the
- 11 Department of Housing and Urban Development relies
- on EPA's renovation, repair, and painting rule in
- its regulation of renovators working in housing
- units, receiving HUD housing assistance where lead
- 15 paint is present.
- 16 EPA calculated the reference dose for
- 17 methyl mercury that EPA and the Food and Drug
- 18 Administration used to create guidelines on fish
- 19 consumption, including recommendations for
- 20 pregnant and breast-feeding women.
- It does not appear that EPA has
- undertaken the required interagency review process

- 1 to assess the implications of its rule for other
- 2 agencies.
- Another neurotoxicant of concern for
- 4 reproductive health is the pesticide,
- 5 chlorpyrifos. Researchers followed a cohort of
- 6 children exposed to this pesticide before the
- 7 current ban on indoor use and found lower IQ and
- 8 working memory to be associated with higher levels
- 9 of prenatal chlorpyrifos exposure.
- In a rulemaking process regulating
- 11 agricultural use of chlorpyrifos, EPA requested
- 12 the underlying data from the Columbia Center for
- 13 Children's Environmental Health. The response
- 14 from Columbia University explained that because of
- the detailed sociodemographic and health-related
- 16 elements their data set contains, they did not
- 17 believe they could submit extensive individual-
- 18 level data to EPA in a way that would ensure
- 19 participants' confidentiality.
- 20 Such concerns are not uncommon with the
- 21 kids of longitudinal data sets that allow
- identification of long-term consequences of

- 1 environmental exposures. Often, the combination
- 2 of variables used in an analysis provides enough
- 3 information to identify individual participants
- 4 and may include sensitive information, such as
- 5 diagnosis of neurodevelopmental delays.
- In addition, endocrine disrupting
- 7 chemicals are of great concern and reproductive
- 8 health and EPA has regulated some of these, such
- 9 as PCBs and PBDEs, under the Toxic Substances
- 10 Control Act.
- 11 Under reformed TSCA, EPA must make
- decisions based on the weight of the scientific
- evidence, but it is not clear how it can do so if
- 14 studies may be eliminated from consideration
- 15 because data sets are not publicly available.
- 16 If EPA moves forward with the rule it has
- 17 proposed, it will undermine science and regulatory
- 18 decision-making by making it difficult and
- 19 potentially impossible to consider the best
- 20 available science. This will have detrimental
- 21 impacts on reproductive justice, health equity,
- 22 and women's health. The Jacobs Institute of

- 1 Women's Health urges EPA to withdraw this rule.
- MR. ROBBINS: Thank you.
- MS. NOLEN: Hi. Thank you. My name is
- 4 Janice Nolen. It's J-A-N-I-C-E N-O-L-E-N, and I
- 5 am the National Assistant Vice President for
- 6 Policy for the American Lung Association.
- 7 The American Lung Association turns 114
- 8 years old this year. For more than a century we
- 9 have fought to save lives for protecting lung
- 10 health and preventing lung disease. We oppose the
- 11 proposed rule.
- Many years ago, in the early 1980s, my
- mother-in-law asked me to help her recruit
- 14 participants in a major new study that they were
- 15 doing. She worked for the American Cancer Society
- 16 then. They were looking to create a huge database
- of ordinary Americans would be willing to provide
- 18 them with confidential information about their
- 19 health and medical experiences, and would allow
- them to track those for years to come.
- I was so pleased that two men from my
- 22 church choir in Nashville agreed to participate.

- 1 They completed the forms and other paperwork, and
- 2 became two of the more than half million
- 3 participants in the cancer prevention study too.
- Fast-forward a decade or so and I learned
- 5 that their data were now part of a landmark study,
- 6 the American Cancer Society study that revealed
- 7 the risks to human health from breathing air
- 8 pollution that I and my colleagues at the lung
- 9 association were working hard to clean up.
- Their data and private health and medical
- information, from hundreds of thousands of others
- were -- from hundreds of thousands of other
- 13 people, who were pointing the way, the need to
- 14 clean up emissions from power plants, from diesel
- 15 engines and fuels, and many other sources. I
- never dreamed when my mother-in-law made her first
- 17 request to me that EPA scientists and other
- 18 researchers would mark that study as one of two
- 19 seminal studies that helped reshape our
- 20 understanding of the health risks from particulate
- 21 matter air pollution.
- None of us then would have ever dreamed

- 1 that the information these two men provided would
- 2 have helped to identify and underline the threat
- s to human life posed by microscopic particles in
- 4 the air we breathe.
- 5 Furthermore, that study and the Harvard
- 6 Six Cities Study became examples, not only of
- 7 ground-breaking research, but of how questions
- 8 about that research can be reviewed and resolved
- 9 without having to lose the entire study.
- 10 Unfortunately, that is an example that
- 11 this proposal clearly fails to understand. These
- 12 two studies with decades-old patient data and
- others in the long list of studies that found
- 14 evidence of harm from industrial emissions are
- unique events that no one hopes to replicate, like
- 16 gulf oil spills, clearly appear to be targets of
- 17 this proposed rule.
- Studies that have been -- long been
- 19 targets of industry polluters and their allies,
- 20 remains so in this proposal.
- Once published, these studies raised
- 22 alarms in the public health community about the

- 1 increased likelihood of premature death from
- 2 particulate matter, widespread in the nation. The
- 3 studies raised alarms within industry too, about
- 4 the increased likelihood that their polluting
- 5 sources would have to clean up their emissions.
- 6 Industry kicked in messaging developed by the
- 7 tobacco industry, to challenge the science using
- 8 the same arguments we have in this proposal.
- I have in my office, a page from a 1999
- 10 U.S. News and World Report article on the
- 11 challenges to these studies that could have been
- written this year.
- Scientists are working to become more
- 14 transparent in their research. More researchers
- use publicly available information, but some
- 16 studies cover populations that are so limited in
- 17 size or specialized in their characteristics that
- 18 these data could not be posted on the web for all
- 19 the world to see. Anyone who has an account on
- 20 Facebook should have a visceral knowledge of how
- 21 important keeping confidential data confidential
- can be.

- 1 Meanwhile, EPA could readily review
- 2 historical data and studies in ways that respect
- 3 patient confidentiality and the gifts of data from
- 4 people like my two choir member friends.
- So far, EPA has failed to show any reason
- 6 that these changes are needed in the current
- 7 system. Failed in its own transparency on this
- 8 issue, in fact since EPA has not sought SAB review
- 9 of this, and has not provided sufficient rationale
- 10 for why EPA needs this change, much less how they
- 11 would this rule going forward.
- We request EPA to withdraw this proposal.
- 13 Thank you.
- MR. ROBBINS: Thank you.
- MS. HALL: Would Speaker Number 40,
- 16 Albert Donnay, come to the speaker's table. And
- 17 Speaker Number 41, Mona Sarfaty.
- MR. DONNAY: Thank you. My name is
- 19 Albert Donnay. My comments are based on
- 20 experience gained from 40 years working on
- regulatory science as an environmental health
- 22 engineer and toxicologist, as a research

- 1 scientist, public health activist, clinician,
- 2 consultant, peer-reviewer for academic journals,
- 3 environmental groups and government agencies at
- 4 all levels, including EPA.
- 5 I'm glad I get to follow the last two
- 6 speakers because I want to highlight that although
- 7 EPA's proposal to "Strengthen Transparency in
- 8 Regulatory Science" is needed, did not give any
- 9 examples of regulations that had been undermined
- 10 by a lack of such transparency.
- I want to remind everyone here what's at
- 12 stake and what happened the first time EPA,
- 13 congress, and environmental groups had to decide
- 14 whether it was okay to base regulatory standards
- on published scientific studies whose achieves
- were no longer available for review.
- 17 They got the answer right then, and I
- 18 hope they'll get it right again now. It was May,
- 19 1983, 35 years ago, and the EPA was about to
- 20 publish a new national ambient air quality
- standard for carbon monoxide based on nine studies
- 22 by a distinguished cardiologist at the VA, Dr.

- 1 Aronow. When the Washington Post reported that
- 2 he'd been barred by FDA a year earlier for
- 3 submitting a wave of false medical experiments
- 4 after he admitted, quote, "fudging his lab reports
- 5 in human drug studies."
- 6 Although EPA's head of the Office of Air
- 7 Quality Planning and Standards said the Agency
- 8 had, quote, "No reason to believe anything was
- 9 wrong with Aronow's CO studies," whose data Aronow
- 10 claimed at the time, "are excellent and can't be
- 11 questioned." EPA nevertheless appointed a special
- 12 team of agency and outside scientists to review
- 13 his work, quote, "When we read that Aronow had
- 14 done some kooky things."
- A month later, The Post reported the
- 16 shocking results under the headline, "EPA Probe
- 17 Criticizes a Study Used in Air-Quality Standard."
- 18 The team had said, quote, "Could not resolve the
- issue of possible falsification of data because,"
- 20 quote, "no data were available." Aronow told them
- 21 he'd discarded the archives of all of his CO
- 22 studies after first storing them in his garage for

- 1 years, and offering it to EPA because they didn't
- 2 want it.
- The investigators noted considerable
- 4 concerns about the validity of the results
- 5 reported, quote, "Raw data were lost or discarded.
- 6 Adequate records were not maintained, available
- 7 data were of poor quality, and quality control was
- 8 nonexistent."
- 9 And Aronow's published results were
- 10 consistently too good to be true. They found it,
- 11 quote, "Rather remarkable that in 10 years of
- research his papers showed," quote, "not even one
- 13 missing data point." They concluded that EPA,
- 14 quote, "Cannot rely on Aronow's data due to the
- 15 concerns we've noted." And they recommended the
- 16 Agency commission new research to attempt to
- 17 replicate Aronow's findings.
- 18 Congressional hearings and the GAO
- investigation followed, after which Administrator
- 20 Ruckelshaus agreed that EPA would not rely on any
- of Aronow's studies in future rulemakings, but
- 22 only on studies whose archives were still

- 1 available for review.
- In coordination with the California Air
- 3 Resources Board and the Health Effects Institute,
- 4 EPA commissioned a series of new controlled human
- 5 exposure studies on CO, and since 1994, has based
- 6 the CO NAAQS exclusively on just six of them, all
- 7 of which published their individual results in
- 8 deidentified form so they would be available for
- 9 public review in perpetuity.
- And it's a good thing they did since all
- 11 the larger archives of these studies were
- 12 eventually discarded by their authors without
- 13 being offered to EPA. This history shows that EPA
- 14 can and should base regulations solely on studies
- whose methods and data are available for review.
- 16 To base regulations on studies that can't be
- 17 reanalyzed is not science, and there is no need
- 18 for it. Even federal rules that are based on
- older epi studies, like the last particulate NAAQS
- 20 rule in 2013 that cited just six studies could and
- 21 should be based on more recent research that
- 22 better reflects current air quality.

- Over 500 studies a year are now published
- 2 on particulate epidemiology, and many are in high
- 3 quality journals that require authors at least to
- 4 make all their deidentified data and methods
- 5 available to reviewers, if not to all readers from
- 6 the posting of supplemental material.
- 7 Given EPA's interest in basing
- 8 regulations on more transparent research, EPA
- 9 should start requiring all the researches it
- 10 funds, intermural and extramural, to publish their
- 11 results in such journals. Hopefully this will
- 12 prompt less rigorous journals that don't require
- 13 the posting of supplemental material to update
- 14 their policies.
- In conclusion, the Aronow scandal shows
- 16 EPA cannot rely exclusively on traditional peer
- 17 review to detect misconduct. Aronow reviewers at
- 18 11 leading journals, as well as EPA staff and
- 19 their scientific advisors on the CASAC, who also
- 20 review the studies before recommending that nine
- 21 be cited as the basis for the CO NAAQS.
- 22 Unfortunately, despite all this publicity, none of

- 1 Aronow's studies were retracted, and the EPA has
- 2 started citing them again, most recently in the
- 3 2010 integrated science assessment of the CO
- 4 literature.
- 5 EPA's proposal to strengthen transparency
- 6 and regulatory science could stop this from
- 7 happening again, which is why I support it and
- 8 encourage my colleagues to do so as well. Thank
- 9 you.
- MR. ROBBINS: Thank you.
- MS. SARFATY: Can you hear me?
- MR. ROBBINS: Yes.
- MS. SARFATY: Yeah. Okay. Respected EPA
- 14 panelists and fellow citizens, my name is Mona
- 15 Sarfaty. I'm a physician trained in family
- 16 medicine and public health. I practice primary
- 17 care medicine and taught medical and public health
- 18 students in three different academic medical
- 19 centers for 35 years.
- Today I direct a program in climate and
- 21 health at George Mason University in Fairfax,
- 22 Virginia. I also direct a consortium of physician

- 1 societies called the Medical Society Consortium on
- 2 Climate and Health, whose 550,000 members are more
- 3 than half the physicians in the United States.
- 4 The Consortium seeks to inform the public
- 5 and policy makers about the health harms of
- 6 climate change, and the health benefits of climate
- 7 solutions. I'm submitting the formal comment of
- 8 the consortium in written form in a separate
- 9 document.
- The EPA is proposing to change the rules
- 11 that dictate what evidence must be considered as
- 12 the basis for protecting the public's health. As
- a physician who spent a summer in Southern
- 14 California during college and didn't see Mount
- 15 Wilson looming in front of me for an entire week
- 16 because of smog, I am incredulous.
- I remember well the pain in my chest when
- 18 trying to play tennis on those smoggy days. This
- was the early 70s, when a republican president was
- 20 creating the EPA. Now, 50 years hence, tremendous
- 21 evidence has accumulated that validates my
- 22 symptoms and the negative effect that unhealthy

- 1 hair -- air, has on people who must breathe it.
- 2 After that summer, as a practicing
- 3 physician, I took care of people with asthma and
- 4 chronic lung disease who were at greater risk on
- 5 bad air days. So it is shocking to me that the
- 6 EPA would propose putting aside huge amounts of
- 7 thoroughly reviewed evidence on the causal
- 8 connections between air pollution and poor health,
- 9 claiming that the basis for this conclusion was
- 10 secret.
- 11 Today, I lead a consortium comprised of
- 12 the country's largest medical societies whose
- doctor members are highly concerned about the
- 14 health harms of climate change. The similarities
- 15 between the current EPA willingness to disregard
- 16 established science about the connection between
- 17 carbon dioxide and global warming, and the
- 18 willingness to disregard solid evidence about the
- impact of air pollution on health, are glaring.
- Despite overlapping evidence from every
- 21 country in the world, and the entire U.S. climate
- 22 science enterprise, not to mention major federal

- 1 agencies like NOAA and NASA, the EPA leadership
- 2 does not accept or recognize reality.
- To all of us whose lives are dedicated to
- 4 helping people get and stay healthy, there is a
- 5 secret lurking in the science of air pollution and
- 6 global warming. It is not what we have long-known
- 7 about how burning fossil fuels creates waste
- 8 products that damage and inflame our lungs. This
- 9 has been validated by voluminous overlapping
- 10 research studies. The secret is not that carbon
- 11 emissions from burning fossil fuels are warming
- our climate, exacerbating the health harms of air
- 13 pollution, and causing other dangers to our
- 14 health, from heat waves, wild fires, pollen, and
- 15 storms.
- The secret is hiding in plain sight.
- 17 Fighting air pollution is the greatest public
- 18 health opportunity of our time. It's the greatest
- 19 public health opportunity of our time.
- 20 Reducing polluting fumes and emissions
- 21 from fossil fuels will rapidly improve our health
- 22 and fight climate change.

- When an EPA's not so secret agenda is to
- promote fossil fuels, two things follow. The fact
- 3 that fossil fuels are the major contributor to
- 4 both air pollution and global warming must be
- 5 undermined or denied. And the research that
- 6 documents this reality and how it harms our health
- 7 must be attacked. It's not hard to see that the
- 8 approach is to mislead people by wrapping these
- 9 attacks in rhetoric that's alternatively scary as
- 10 in secret science, and high-minded, as in
- 11 transparency.
- We're told that the rationale for the new
- 13 proposed strengthening transparency standard is
- 14 that individual and medical records included in
- 15 research were secret. In fact, like all medical
- 16 records, they were confidential and they remain
- 17 SO.
- The record shows that the same argument
- of secrecy against scientific studies has been
- 20 used by polluting industries going back many
- 21 years.
- Health providers know that the facts may

- 1 be scary when our health is threatened. But we
- 2 also know that denying or ignoring facts blinds us
- 3 to discovering and acting on the best ways to heal
- 4 medical problems and protect our health. We can't
- 5 let that happen. The EPA must live up to its
- 6 charge and work to face facts and protect our
- 7 environment and our health. With this proposed
- 8 regulation, its leadership is pointing in the
- 9 opposite direction. Thank you.
- MR. ROBBINS: Thank you.
- Okay. We're going to take a short recess
- now and we'll resume at noon.
- [Morning session adjourned.] [On the
- record 12:00 p.m., Afternoon session.]
- MS. RADZIKOWSKI: Good afternoon. If everyone
- 16 will please take their seats? Hello, and thank
- 17 you for coming. My name is Mary Ellen Radzikowski
- 18 and I am in the EPA's Office of Research and
- 19 Development and I'm one of the hearing officials.
- 20 Joining me is Lynn Flowers, also from the Office
- of Research and Development and we have a number
- of folks: Nanishka Albaladejo, Lauren Hall and

- 1 Lesley Stobert from SC&A Inc., helping with
- 2 logistics.
- 3 The purpose of today's hearing is to accept public
- 4 comments on the EPA proposed rule, "Strengthening
- 5 Transparency in Regulatory Science". EPA is
- 6 accepting comments on all aspects of the proposed
- 7 regulation. This public hearing is a formal legal
- 8 proceeding and the testimonies will become part of
- 9 the administrative record on which EPA will base
- 10 its decision.
- 11 Public notice of this hearing was published in the
- 12 Federal Register on April 30, 2018 (83 FR 18768).
- 13 EPA is proposing this rule under the authority of
- 5 U.S.C. 301, in addition to the authorities
- 15 listed in the proposed rule document dated April
- 16 30, 2018.
- 17 My role is to ensure that the EPA receives your
- 18 comments in an orderly fashion. Although EPA
- 19 panel members here may ask clarifying questions,
- 20 the intent of the hearing is to listen to your
- 21 comments, not to discuss or debate the proposal.
- Now I will go through a few housekeeping items and

- 1 ground rules: Please refrain from interrupting
- speakers or asking questions. Shouting,
- 3 noisemaking or any disruptive conduct which
- 4 prevents speakers or hearing officials from being
- 5 heard are not permitted. Please listen quietly so
- 6 that we can hear each testimony and to ensure that
- 7 the court reporter is able to record comments
- 8 accurately and listeners on the phone hear the
- 9 oral testimonies. For everyone's awareness, this
- 10 hearing is open to the press and we may have
- 11 members of the media present with us today. This
- event is also open to any form of recording,
- video, audio and photos. We ask that you not
- 14 cause any disruption to those testifying or
- observing the hearing.
- 16 There is no formal lunch break scheduled. You may
- 17 leave and return to the hearing. Please note that
- 18 you will need to clear security again so please be
- 19 aware of the time.
- 20 If you would like to make an oral comment at
- today's hearing and did not pre-register to speak,
- 22 please see the hearing staff at the registration

- 1 table located right outside the doors here. If
- 2 you would like to provide a written comment for
- 3 the official record, you may hand-submit it to EPA
- 4 staff today, or mail, fax or email your comments.
- 5 See the staff at the registration table for
- 6 instructions on how to do that. There is a
- 7 comment box at the registration table where you
- 8 can leave hardcopies of your oral testimony or
- 9 written comments. All comments received will be
- 10 included in the official docket. If you submit
- 11 written comments, it is not necessary for you to
- 12 give the same comments orally; written comments
- and oral testimonies will receive equal
- 14 consideration by EPA in preparing its final
- 15 rulemaking decision.
- 16 EPA has extended the comment period. Written
- 17 comments must now be received on or before August
- 18 16, 2018. EPA will only consider comments related
- 19 to the proposed rule, "Strengthening Transparency
- 20 in Regulatory Science", so please refrain from
- 21 making comments that are not related to this
- 22 action.

- 1 EPA will not be providing responses during the
- 2 hearing. Rather, EPA will prepare a written
- 3 summary of the comments received that includes
- 4 responses.
- 5 The summary of the Response to Comments, the
- 6 document, will be available at the time EPA issues
- 7 its final decision. EPA will not make a final
- 8 decision until all comments submitted during the
- 9 public comment period have been considered.
- 10 The hearing is being recorded by a court reporter,
- 11 who will be preparing a verbatim record of this
- 12 hearing.
- 13 Please speak clearly and slowly into the
- 14 microphone so that the court reporter can
- 15 accurately record your comments. A copy of the
- 16 transcript will be placed in the docket. This
- 17 hearing is also being audio streamed through Adobe
- 18 Connect via the telephones.
- 19 The hearing is scheduled -- started at 8 AM this
- 20 morning and is scheduled to go to 8 PM. We're in
- the second session: 12pm-4pm.
- 22 Public restrooms are located down both sides of

- 1 the hall. At the doors we have staff that can
- 2 escort you out and back. Please note the location
- 3 of the emergency exits. Please take a moment to
- 4 silence your cell phones.
- 5 Speakers should have been given a sticker upon
- 6 check-in that lists your assigned session. If you
- 7 plan to speak and have not received a sticker,
- 8 please be sure to check in at the registration
- 9 table. For this session, the speaker sticker
- 10 color is white, so if you have a white sticker
- 11 you're registered for this session.
- 12 Speakers will be called to the speakers' table
- 13 (located right over there) in pairs by their
- 14 speaker number.
- 15 When it is your turn to speak, please come to the
- 16 table, state and slowly spell your name for the
- 17 record, and if you are appearing on behalf of
- 18 someone or another organization. If you are not
- in the room when it is your turn to speak, I will
- 20 recall you after all other speakers have made
- their oral comments. Each speaker will be
- 22 allotted 5 minutes for remarks. Elected and

- 1 appointed government officials may be provided
- 2 additional time, since they represent large groups
- 3 of constituents. Speakers will be notified when
- 4 their time has ended. Our timekeeping system
- 5 consists of green, yellow, and red lights. When
- 6 you begin to speak, the green light will come on
- 7 to indicate you have your 5 minutes. The yellow
- 8 light indicates that you have 1-minute left and
- 9 when the red appears, your 5 minutes are over. At
- 10 that moment, if needed, I will politely interrupt
- 11 you and ask you to wrap-up your testimony to give
- others an opportunity to speak.
- 13 At this time, we are going to begin.
- 14 MS. STOBERT: If Speakers Numbers 1, Pamela
- 15 Miller, and 2, Elizabeth Geltman, will come to the
- 16 speakers table and Speakers 3 and 4, Patricia
- 17 Koman and Alexis Adiman would go to the on-deck
- 18 seating located near the stage.
- 19 MS. MILLER: Good afternoon, my name is Pamela
- 20 Miller, P-A-M-E-L-A, M-I-L-E-R. I serve as
- 21 Executive Director and provide these comments on
- 22 behalf of Alaska Community Action on Toxics.

- 1 We're a nonprofit, public interest environmental
- 2 health, research and advocacy organization,
- 3 dedicated to protecting public health. I also
- 4 serve as principle investigator of multiyear
- 5 research studies involving several universities
- 6 that investigate exposures and health outcomes
- 7 concerning endocrine-disrupting chemicals in
- 8 collaboration with Arctic indigenous communities
- 9 in Alaska. I traveled the distance to Washington,
- 10 D.C., from St. Lawrence Island, Alaska, in the
- 11 Northern Bering Sea, two full days of travel,
- where we are conducting summer field research and
- interrupted this because EPA did not make it
- 14 possible to provide remote testimony.
- 15 Through a process known as global distillation,
- 16 the Arctic has become a hemispheric sink for
- 17 contaminants that are carried on atmospheric and
- oceanic currents into the north where they
- 19 concentrate in the bodies of fish, wildlife and
- 20 people. Indigenous peoples of the Arctic are
- 21 among the most highly exposed populations on Earth
- to persistent bio-cumulative and toxic chemicals

- 1 because of their reliance on traditional foods
- 2 including fish and marine mammals that they use
- 3 for their spiritual, cultural and physical
- 4 sustenance. The communities that I work with on
- 5 St. Lawrence Island also have higher exposures to
- 6 chemical contaminants from military operations
- 7 associated with formerly used defense sites. Our
- 8 research elucidates exposure pathways, body
- 9 burdens and health outcomes associated with
- 10 chemicals including PCBs, PBDEs (or polybrominated
- 11 diphenyl ethers) and other flame retardants and
- 12 also perfluorinated substances in homes, in air,
- water, traditional foods and in the blood serum of
- 14 the Yupik people of St. Lawrence Island. Our
- 15 studies have shown elevated body burdens as well
- 16 as disruption of thyroid function associated with
- 17 these exposures to certain PBDEs and
- 18 perfluorinated substances. We are now beginning a
- 19 research study to investigate exposures to PCBs,
- 20 PBDEs and currently used organophosphate flame
- retardants in young Yupik children, age 2 to 12,
- 22 because elders and other community leaders are

- 1 concerned about possible adverse effects on
- 2 children's neurodevelopment. They're concerned
- 3 that chemical exposures might harm the children's
- 4 abilities to learn the languages, songs and
- 5 stories that are so vital for the continuance of
- 6 the culture of Yupik people. Participation is
- 7 dependent on the trust of confidentiality that
- 8 they give to us as researchers. Our research team
- 9 submits each proposal to rigorous review to the
- 10 National Institute of Environmental Health
- 11 Sciences. In the process of the research, we
- 12 submit also to several institutional review boards
- 13 for approval to collect sensitive and detailed
- information on health and behavior as well as
- 15 spatial and demographic data in an ethical manner
- 16 that protects human subjects. We have published
- 17 results of our research in 11 peer-reviewed
- 18 journal articles after receiving approval from the
- 19 tribal leadership. These findings help inform
- 20 interventions and policies to reduce burdens of
- toxic exposures and prevent further harm to public
- 22 health. These studies are possible only because

- 1 we quarantee to protect the medical privacy of
- 2 participants, again dependent on trust of the
- 3 researchers. We gather detailed information about
- 4 peoples' health and occupational histories,
- 5 practices in their homes and communities that
- 6 might relate to chemical exposures. If the
- 7 proposed rule were to go into effect, studies such
- 8 as these would not be considered by EPA when it
- 9 makes decisions about chemicals and pollutants
- 10 that are poisoning the people of the Arctic such
- 11 as decisions to limit the production and use of
- 12 persistent biocumulative toxics and other
- 13 chemicals including those regulated under TSCA and
- 14 FIFRA and in regulations that hold military and
- industrial polluters responsible for contamination
- of air, waters and lands under CERCLA, the Clean
- 17 Air Act and the Clean Water Act. EPA indicates
- 18 that the proposed rule is intended to strengthen
- 19 transparency of EPA regulatory science; however,
- 20 we find this a duplicitous claim. It would favor
- industry data protected as confidential business
- information over public peer-reviewed research.

- 1 We support the best scientific evidence to inform
- 2 regulatory decisions. However, this rule would
- 3 have a dangerous counter effect by limiting the
- 4 science that should be used to inform decisions
- 5 about public health. Furthermore, we disagree
- 6 with the agency's conclusions as stated in the
- 7 proposed rule document that this action does not
- 8 have tribal implication as specified in the
- 9 executive order and requiring government to
- 10 consult with tribes. This rule would
- 11 disproportionately affect vulnerable populations
- 12 including American Indian and Alaska Native People
- and, therefore, is relevant and requires
- 14 consultation.
- 15 MS. RADZIKOWSKI: Excuse me, your time is up. We
- 16 need to be fair to others.
- 17 MS. MILLER: I'll wrap up to say that we urge EPA
- 18 to end this rulemaking promptly and we strongly
- 19 oppose the proposal. Thank you.
- 20 MS. RADZIKOWSKI: Thank you.
- 21 MS. GELTMAN: Good afternoon. Thank you for the
- opportunity to comment on EPA's proposal entitled,

- 1 "Strengthening Transparency in Regulatory
- 2 Science." My name is Elizabeth Glass Geltman, G-
- 3 E-L-T-M-A-N. I am a Professor of Environmental
- 4 Health Policy at the City University of New York -
- 5 the CUNY School of Public Health, located in
- 6 Harlem. I am the author of 17 books on
- 7 environmental and natural resources policy, a
- 8 peer-reviewer of numerous journals and have worked
- 9 on EPA-regulated matters for over 30 years. I am
- 10 also the Chair Elect of the Law Section of the
- 11 American Public Health Association. As a
- 12 professor, I aim to advance public health by
- 13 preventing people from getting sick. My efforts
- 14 address reducing health impacts, and hence
- 15 controlling health costs, by evaluating chemical
- 16 and environmental determinants of health.
- 17 Although EPA's rule aims to establish a clear
- 18 policy concerning the use of dose-response data
- 19 and models that underlie pivotal regulatory
- 20 policy, the rule is, in fact, a continuation of
- the Trump administration's two for one regulatory
- reform policy announced in Executive Orders 13771,

- 1 13777, and 13783. The rule promises, "to change
- 2 agency culture and practices regarding data access
- 3 so that scientific justification for regulatory
- 4 actions is truly available for validation and
- 5 analysis." However, the new rule, in fact,
- 6 creates new regulatory hurdles by discounting and
- 7 precluding consideration of long-standing,
- 8 established scientific practice. Rather than
- 9 promoting the transparency of scientific
- 10 information used to create environmental
- 11 regulations, the rule will obscure the democratic
- 12 process, slow the pace of science and progress,
- and potentially prevent important health data from
- 14 being considered by U.S. EPA in outlying important
- 15 environmental policy. Administrative procedure
- 16 requires the EPA consider data submitted by the
- 17 public in evaluating regulations. Let's be clear,
- 18 scientific studies have always been of uneven
- 19 quality. EPA has a process in place, including
- 20 use of Scientific Advisory Board testimony and
- 21 written and oral public notice and comment, using
- internal and external peer review to evaluate

- 1 data. Depending on context some studies are given
- 2 greater weight than others. Some studies are
- 3 disregarded entirely. It is inappropriate,
- 4 however, and unlikely unlawful -- and likely to be
- 5 unlawful -- under the Administrative Procedure
- 6 Act. For EPA to categorically eliminate certain
- 7 types of studies, and hence certain types of data,
- 8 without considering context. But, even more
- 9 important, eliminating studies, unless all
- 10 underlying data is made public, is hazardous to
- 11 human health and the environment. Longitudinal
- medical and epidemiological studies are often
- 13 conducted over years, if not decades. Many
- 14 studies require people who are study subjects to
- 15 share very, very personal information, often on
- 16 the legal or ethical condition that private
- 17 medical information provided will be protected
- 18 from public view. EPA is not, and has never been,
- in the regular business of replicating studies.
- 20 Timing and the cuts in EPA funding make
- 21 replicating studies as a condition of promulgating
- regulations an impossibility. EPA has presented

- 1 no scientific reason to prevent use of human
- 2 health studies simply because the underlining
- 3 medical records are not available for public
- 4 inspection and review. One size fits all rarely
- 5 works in fashion and it is even more unworkable in
- 6 science and regulation. It is imperative the EPA
- 7 allow consideration of all available scientific
- 8 data pertinent to a proposed environmental rule or
- 9 regulation including random, controlled human
- 10 health trials and other epidemiological studies.
- 11 Eliminating certain classes of human health
- 12 studies would be like picking NFL players in the
- 13 draft without allowing any scouting reports or
- 14 eliminating the minor league in baseball. It
- doesn't make sense in sports; it makes even less
- sense when we're safeguarding our nation's air,
- 17 water and land. For the reasons stated, I
- 18 respectfully request the EPA withdraw the
- 19 misleadingly-named rule entitled, "Strengthening
- 20 Transparency in Regulatory Science." Thank you
- very much for allowing me to speak. My comments
- 22 are my own. I'm happy to answer questions and I